

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

Salicylates reportedly displace sulfonureas, 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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Intermediate Prescribing Information

Lioresal®

(baclofen)

Muscle relaxant

Antispastic agent

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, tricyclic antidepressants, 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).

Availability

LIORESAL (baclofen) 10 mg tablets.

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.
Product Monograph supplied on request.

References:

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

G-3017

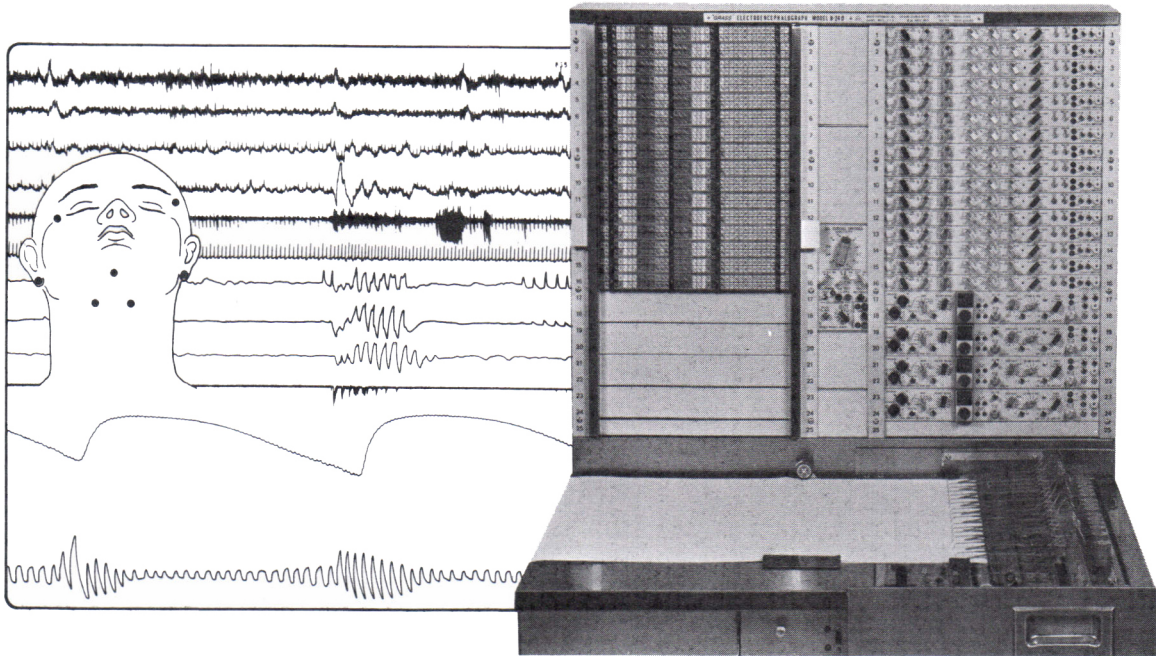
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Tegretol® 200 mg

(carbamazepine)

For Symptomatic Relief of Trigeminal Neuralgia Anticonvulsant**Action:**

TEGRETOL (carbamazepine) has anticonvulsant properties which have been found useful in the treatment of psychomotor and other partial epilepsies, when administered in conjunction with other anticonvulsant drugs to prevent the possible generalization of the epileptic discharge. A mild psychotropic effect has been observed in some patients, which seems related to the effect of the carbamazepine in psychomotor or temporal lobe epilepsy. TEGRETOL relieves or diminishes the pain associated with trigeminal neuralgia often within 24 to 48 hours.

Indications and Clinical Use**A. Trigeminal Neuralgia:**

For the symptomatic relief of pain of trigeminal neuralgia only during periods of exacerbation of true or primary trigeminal neuralgia (tic douloureux). Do not use 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 ineffective in controlling petit mal, minor motor, myoclonic and predominantly unilateral seizures, and does not prevent the generalization of epileptic discharge.

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.

Contraindications

Hepatic disease, serious blood disorder, less than 14 days either before or after monoamine oxidase inhibitor (then the dosage of TEGRETOL should be low initially, and increased very gradually), atrioventricular heart block, hypersensitivity to tricyclic compounds, lactation, first trimester of pregnancy.

Usage in Pregnancy

As safety has not been established, 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.

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 and frequent clinical and laboratory supervision should be maintained throughout treatment. If any signs or symptoms or abnormal laboratory findings suggestive of blood dyscrasia or liver disorder occur, TEGRETOL should be immediately discontinued.

Urinary Retention and Increased Intraocular Pressure:

Caution is advised in patients with increased intraocular pressure or urinary retention due to the drug's anticholinergic action.

Occurrence of Behavioural Disorders:

TEGRETOL may activate a latent psychosis, or, in elderly patients, produce agitation or confusion. Caution is advised in alcoholics.

Use in Patients with Cardiovascular Disorders:

Caution is advised in patients with a history of coronary artery disease, organic heart disease, or congestive failure. An E.K.G. should be performed if a defective conductive system is suspected before administering TEGRETOL, in order to exclude patients with atrioventricular block.

Use in Patients taking Oral Contraceptives:

Women under treatment with TEGRETOL and oral contraceptives, should be advised to use some alternative, non-hormonal method of contraception as the reliability of oral contraceptives may be adversely affected.

Driving and Operating Hazardous Machinery:

Warn patients about the possible hazards of operating machinery or driving automobiles as dizziness and drowsiness are possible side effects of TEGRETOL.

Adverse Reactions

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

Hepatic Disturbances: Abnormalities in liver function tests, cholestatic or hepatocellular jaundice.

Dermatological Reactions: 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: Vertigo, dizziness, somnolence, disturbances of coordination, confusion, headache, fatigue, blurred vision, transient diplopia and oculomotor disturbances, speech disturbances, abnormal involuntary movements, increase in motor seizures, peripheral neuritis, paresthesia, depression with agitation, talkativeness, nystagmus, tinnitus, paralysis and other symptoms of cerebral arterial insufficiency.

Cardiovascular Systems: Recurrence 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, impotence, elevation of BUN, albuminuria, and glycosuria.

Digestive Tract: Nausea, vomiting, gastric or abdominal discomfort, diarrhoea, anorexia, 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 fundoscopy and tonometry, are recommended.

Other Reactions: Fever and chills, lymphadenopathy, aching joints and muscles, leg cramps and conjunctivitis.

Symptoms and Treatment of Overdosage

Symptoms: Dizziness, ataxia, drowsiness, stupor, nausea, vomiting, restlessness, agitation, disorientation; tremor, involuntary movements, opisthotonos, abnormal reflexes (slowed or hyperactive); mydriasis, nystagmus; flushing, cyanosis, urinary retention, hypotension, hypertension, coma. The EEG may show dysrhythmias. The laboratory findings have included leukocytosis, reduced leukocyte count, glycosuria and acetonuria.

Treatment: No known specific antidote. Induce emesis. Perform gastric lavage. Watch vital signs and administer symptomatic treatment as required. Hyperirritability may be controlled by the administration of parenteral barbiturates. Barbiturates should not be used if monoamine oxidase inhibitors have also been taken by the patient, either in overdosage or in recent therapy (within two weeks). Barbiturates may induce respiratory depression, particularly in children, therefore, have equipment available for artificial ventilation and resuscitation. Paraldehyde may be used to counteract muscular hypertonus without producing respiratory depression.

Treat shock (circulatory collapse) with supportive measures, including intravenous fluids, oxygen, and corticosteroids. Electrocardiogram should be monitored, particularly in children, to detect any cardiac arrhythmias or conduction defects.

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. The initial dosage is progressively increased, until the best response is obtained, up to 600 mg daily. Usual Daily Dosage: 600 mg, however 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: Initial daily dosage: 100 mg twice daily may be increased by 200 mg per day until relief of pain is obtained. Usual dosage: 200 to 800 mg daily. Up to 1200 mg daily 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 in trigeminal neuralgia is not recommended. Administer in two or three divided doses daily, with meals whenever possible.

Dosage Forms

TEGRETOL 200 mg
Each white, round, flat, bevelled-edged, double-scored tablet is imprinted with the GEIGY monogram.

Availability

Bottles of 100 and 500 tablets. Protect from heat and humidity. Full information available on request.

References

- 1 Troupin, A.S.: The Choice of Anticonvulsants, Proceedings of the 25th Western Institute on Epilepsy, March 26, 1975, Las Vegas, Nevada.
- 2 Antiepileptic Drugs, Second Edition, Woodbury, Penry, Pippenger, Raven Press, p. 513.
- 3 Thompson, P.J. and Trimble, M.R.: Anticonvulsant Drugs and Cognitive Functions, Epilepsia, 23: 531-544, 1982.

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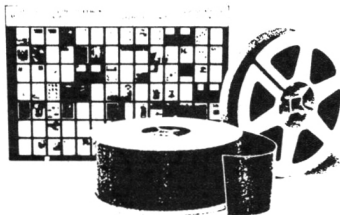
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REFERENCES:

- 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.

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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.

HOW SUPPLIED: Scored tablets of 4 mg each in bottles of 100 tablets.

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Lioresal[®]
baclofen



Treating spasticity right at the start

gives him a
better start on the
tough road back.

Early intervention with Lioresal can significantly enhance successful rehabilitation, especially before major disabilities become permanent!

- Lioresal helps relieve spasticity resulting from spinal cord injury, multiple sclerosis or other spinal cord disorders.
- Lioresal acts primarily at the spinal level eliminating the problem of troublesome over sedation?
- Lioresal improves overall outlook for long term management!

Lioresal[®]

**sooner...
means a
fuller life later.**

For brief prescribing information see page xiv

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Geigy

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