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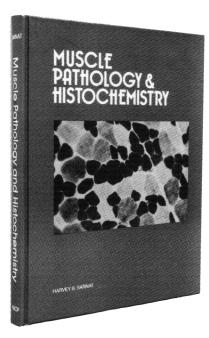
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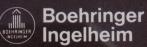
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 S. TEGRETOL is not a simple analgesic and should not be
 used to relieve trivial to respond to TEGRETOL, or
 a s an adjunct, in some patients with secondary or
 partial epilepsy with complex symptomatology or
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 A as an alternative medication in patients with gener alized tonic-clonic seizures who are experiencing
 marked side effects or fail to respond to tother antil convulsant drugs.
 TEGRETOL is ineffective in controling petit mal, minor

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.

ing 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 fre-quent clinical and laboratory supervision should be main-tained throughout treatment. If any signs or symptoms or abnormal laboratory findings suggestive of blood dyscrasia or liver disorder occur, TEGRETOL should be immediately discontinued. discontinued.

discontinued. Urinary Retention and Increased Intraocular Pressure: Caution is advised in patients with increased intraocular pressure or urinary retention due to the drug's anti-cholinergic action. Occurrence of Behavioural Disorders: TEGRETOL may activate a latent psychosis, or, in elderly patients, produce aglitation or confusion. Caution is advised in alcoholics. Use in Patients with Cardiovascular Disorders:

Laboration of the advised of the advised of a laboration of the advised of 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 it 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 con-traceptives, 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 machinery or driving automobiles as dizziness and drowsiness are possible side effects of TEGRETOL.

Adverse Reactions

Adverse Reactions Haematological reactions: Transitory leucopenia, eosino-philia, leucocytosis, thrombocytopenic purpura, agranulo-cytosis, 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 distur-bances, speech disturbances, abnormal involuntary move-ments, 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, syn-cope 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 stomatilis. Eyes: There is no conclusive evidence that TEGRETOL pro-duces pathological channes in the cornea lanes or retina-

Digestive Tract: Nausea, vomiting, gastric or abdominal discomfort, diarrhoea, anorexia, dryness of the mouth and throat, glossitis and stomatilis. Eyes: There is no conclusive evidence that TEGRETOL pro-duces 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 slittamp 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, agliation, 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 bar-biturates. 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, particu-larly in children, therefore, have equipment available for artificial veriliation and resuscitation. Paraldenyde may be used to counteract muscular hypertonus without pro-ducing respiratory depression. Treat shock (circulatory collapse) with supportive measures, including intravenous fluids, oxygen, and corticosteroids. **Design end Administration** *Hes in Eliforesu* (*sea Indications*): A low initial daily dosane

defects.

Dosage and Administration

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. Aduits 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 main-tained, 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 is obtained. Usual dosage: 200 to 800 mg daily. Up to 1200 mg daily may be necessary. As soon as relief of pain 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

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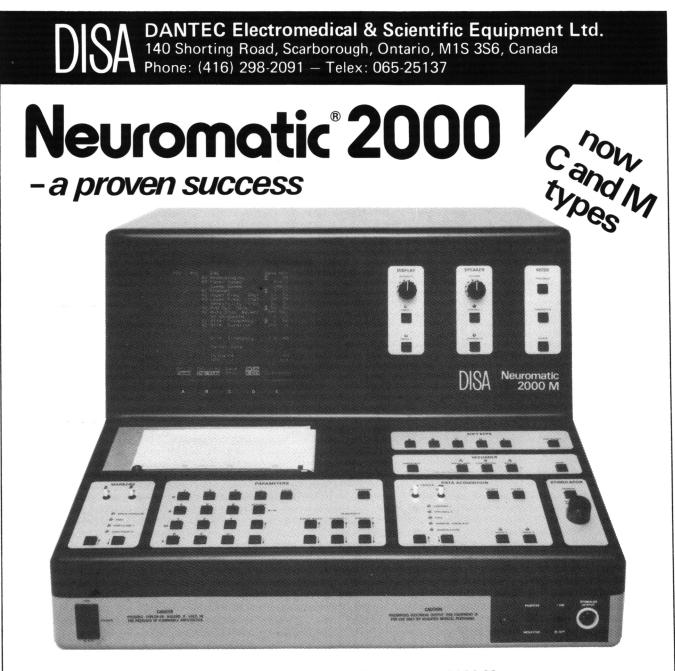
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 Troupin, A.S.: The Choice of Anticonvulsants, Proceedings of the 25th Western Institute on Epilepsy. March 26, 1975, Las Vegas, Nevada.
 Antiepileptic Drugs, Second Edition, Woodbury, Penry, Pippenger, Raven Press, p. 513.
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