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Rivotril®

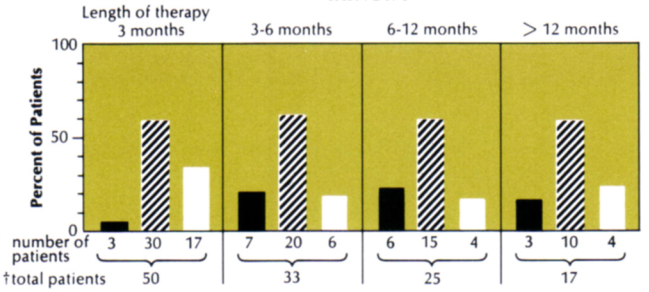
a new oral anticonvulsant from 'Roche' research

RIVOTRIL, with specific and potent anticonvulsant properties, is a new benzodiazepine in the same family as Librium®, Valium® and Dalmane® Roche®. It is therefore characterized by the same high degree of safety and efficacy.

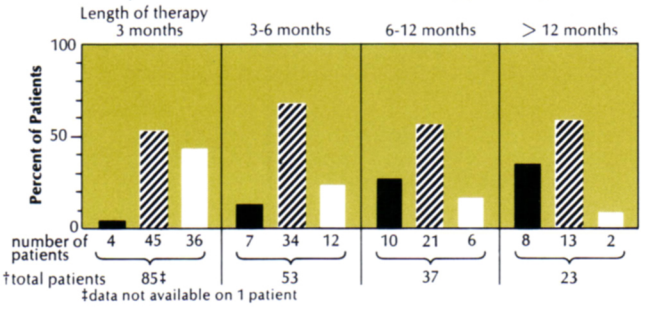
- used alone or as an adjunct, RIVOTRIL can reduce the frequency and/or severity of akinetic, myoclonic and petit mal variant (Lennox-Gastaut syndrome) seizures.
- it may be of value as principal medication in petit mal where succinimide therapy has failed.
- the most frequently noted side effects, drowsiness and ataxia, generally are dose related and can often be controlled by dosage adjustments.

Effect of RIVOTRIL on seizure frequency

Akinetic*

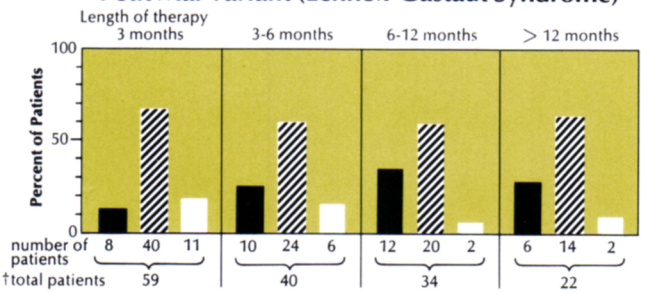


Myoclonic with and without Hypsarrhythmia*

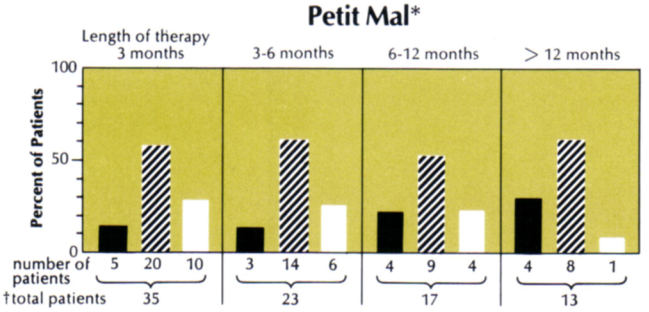


‡data not available on 1 patient

Petit Mal Variant (Lennox-Gastaut Syndrome)*



Petit Mal*



■ Seizures 100% controlled
▨ Seizures better than 50% reduced in frequency
□ Seizures uncontrolled

*Data on file, Hoffmann-La Roche Limited

†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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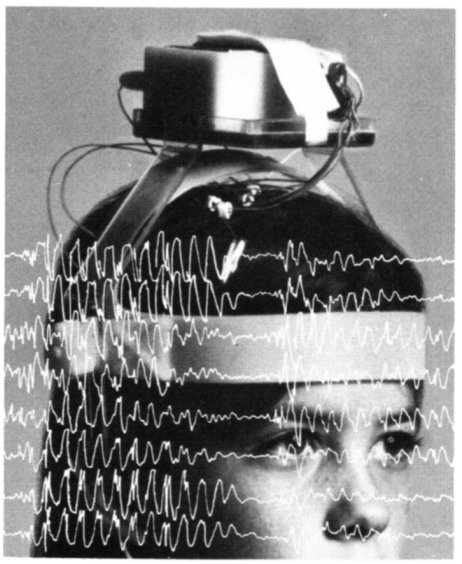
An important aid in the management of minor seizures



Noninvasive EEG telemetry device used to monitor patients in studies evaluating RIVOTRIL.

Rivotril® (clonazepam)

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.

Indications

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).

RIVOTRIL may also be of value in patients with petit mal (absence spells) who have failed to respond satisfactorily to succinimides.

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.

Supply

Scored tablets, 0.5 and 2 mg. Bottles of 100.

®Reg. Trade Marks

Full prescribing information on request.

ROCHE

Hoffmann-La Roche Limited
Vaudreuil, Quebec

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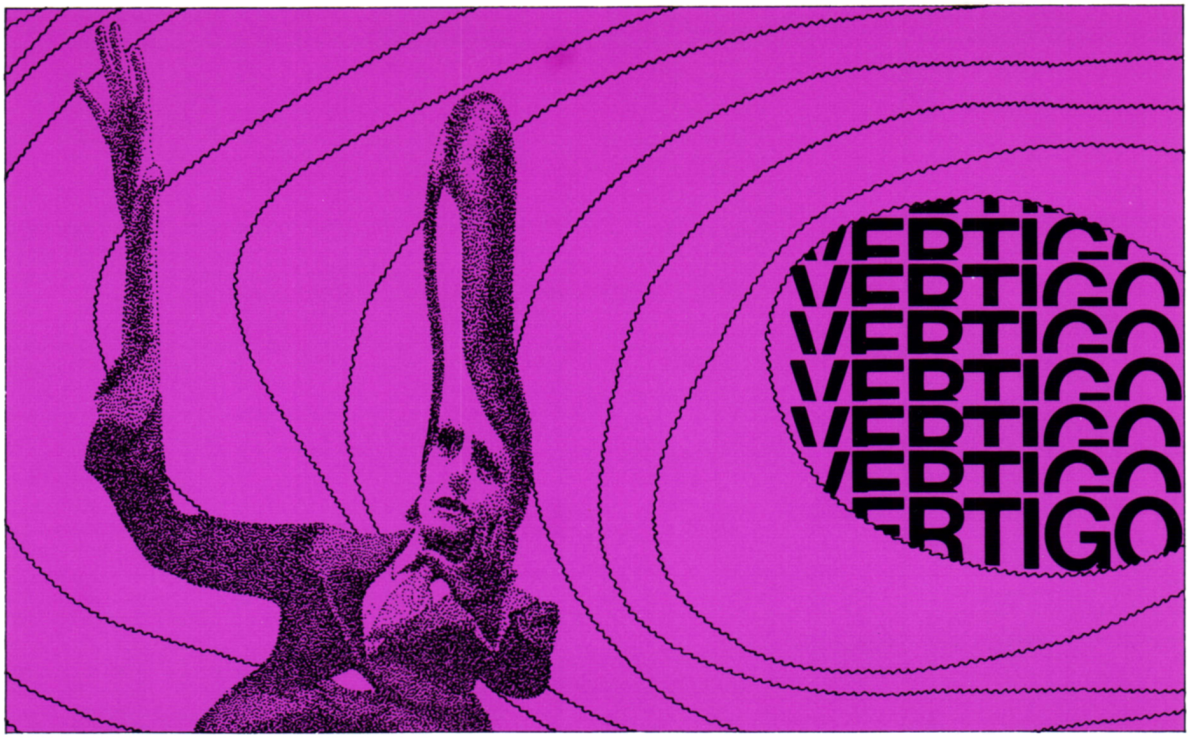
For the management of Vertigo in Meniere's disease



SERC®

(Betahistine hydrochloride) TABLETS

A decade of clinical success in Canada

Chemically Unique Vasoactive Compound

- Vascular responses similar to those of histamine[1, 2]
- Tends to restore, not depress vestibular response[3, 4]

May Increase Blood Flow To Inner Ear

- Increases cochlear blood flow in experimental animals[5, 6]
- Increases basilar and labyrinthine artery flow in canine studies[7, 8]

Demonstrated Efficacy and Patient Acceptance

- Reduces the number and severity of vertigo attacks[9, 10]
- Suitable for long term management[9, 10]
- Effective when other medications failed[9, 10]
- Well tolerated[2, 3, 4, 9, 10]

histaminic – not antihistaminic often a more helpful approach

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1. Hunt, W.H., and Fosbinder, R.J.: A study of some beta-2, and 4, pyridylalkylamines. J. Pharmacol. & Exper. Therap. 75:299 (August) 1942.
2. Horton, B.T., and von Leden, H.: Clinical use of beta-2-pyridylalkylamines. Part I. Proceedings of the Staff Meetings of The Mayo Clinic 37:692 (Dec. 5) 1962.
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9. Guay, R. M.: Meniere's disease (Preliminary report of a new treatment). Applied Therapeutics 12:25 (August) 1970.
10. Hommes, O. R.: A study of the efficacy of betahistine in Meniere's syndrome. Acta oto-laryng. Supplement 305:70, 1972.

PRESCRIBING INFORMATION

DESCRIPTION AND CHEMISTRY: SERC is the proprietary name for a histamine-like drug generically designated as betahistine hydrochloride.
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.
Full Prescribing Information available on request.

UNIMED Pharmaceuticals Limited
Dorval, Québec, H9P 2P4

PAAB
CCPP

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THE CANADIAN JOURNAL OF NEUROLOGICAL SCIENCES
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THE EDITORIAL BOARD wishes to publish original work in the basic and clinical neurosciences on the understanding that it has not been and will not be published elsewhere. Review articles on timely subjects will be accepted. Manuscripts must be in duplicate including illustrations. One of the copies must be the original, ribbon copy. Manuscripts should be typed double spaced, on white paper.

Papers will be accepted in French or English. All papers should be accompanied by a short résumé in both languages. The résumé translation will be done by the editorial board if requested.

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.

ILLUSTRATIONS: Photographs should be unmounted on glossy paper and show magnification scale. They should be marked on the back with figure number, title of paper and name of author.

Diagrams should be in India ink and large enough to be informative after reduction.

All illustrations should be referred to as figures, numbered consecutively, not included in the body of the text and all captions should be typed on a separate piece of paper.

Colored illustrations cannot usually be accepted unless the author is prepared to assist with the cost of reproduction.

REFERENCES to authors outside the context of the sentence should read (Name, Year). *i.e. "However, a recent study (Bird and Iverson, 1975) showed a decreased, etc."* Authors mentioned within the context of the sentence should read Name (Year). *"i.e. . . . twenty years since Ecker and Reimenshender (1951) demonstrated, etc."* References should be typed in alphabetical order on a separate sheet and include author's name, initials, year, title, publication, volume, first and last page, i.e. Isacson, P. (1967). Myxoviruses and autoimmunity. Progress in Allergy, 10, 256-292. Abbreviations should be the same as those used in Cumulated Index Medicus.

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

REPRINTS: Fifty reprints will be supplied free if ordered when the galley proofs are returned. More may be ordered at a nominal charge. Corrections and changes in the galley proofs, apart from printer's errors may be charged to the author.

This journal is indexed by **Index Medicus, Excerpta Medica** and **Current Contents — Clinical Practice and Life Science.**

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Tegretol®
Carbamazepine

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 douloureux). 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 in:

1) 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.

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 an 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.

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.

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.

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 sensitivitiy 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, hypotension, syncope and collapse, edema, aggravation of coronary artery disease. Some of these complications have resulted in fatalities.

Other cardiovascular complications (including myocardial infarction and arrhythmia) have been associated with other tricyclic compounds. Whether all these complications are drug-related is not known at this time.

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 slit-lamp fundoscopy 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 psychomotor and other secondary or partial seizures:
A low initial daily dosage with a gradual increase in dosage is advised. Dosage should be adjusted to the needs of the individual patient.

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 ben 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, single-scored tablet, engraved with signet.

Availability
Bottles of 50 and 500 tablets. Protect from moisture.

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Full information is available on request.

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Progress for the Parkinsonian Patient

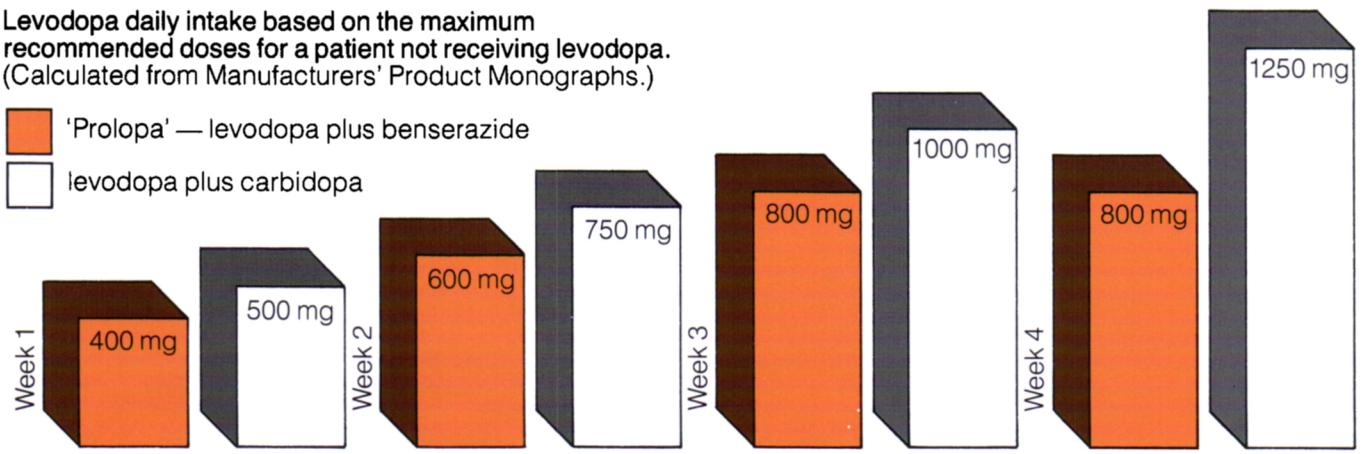
Prolopa®

1971 Roche was the first to introduce levodopa (Larodopa*), a drug which could substantially improve the life of the Parkinsonian patient.

1977 Continuous research and clinical trials enables Roche to introduce 'Prolopa' (levodopa plus the decarboxylase inhibitor benserazide in a 4:1 ratio). 'Prolopa' provides significant advantages for the patient and physician:

- An equal degree of improvement to that obtained with levodopa alone in the signs and symptoms of Parkinson's disease.[1]
- A marked reduction (approximately fivefold) in the daily dosage of levodopa needed to obtain a satisfactory response from patients.[2,3]
- A more rapid clinical response. Maximum benefit achieved in days as opposed to months with levodopa.[4]
- Less frequent occurrences of the side effects of nausea and vomiting with 'Prolopa' than with levodopa only.[5]
- A simpler dosage regimen.[2]
- Within the range of recommended doses, less levodopa is required to reach optimal dosage for most patients than with the combination of L-dopa plus carbidopa.[6]

Levodopa daily intake based on the maximum recommended doses for a patient not receiving levodopa.
(Calculated from Manufacturers' Product Monographs.)



'Prolopa': Initially, one capsule b.i.d., increasing by one capsule every three days to a maximum of eight capsules. Combination of levodopa plus carbidopa: Initially ½ tablet b.i.d., increasing by ½ tablet every three days to a maximum of five tablets.

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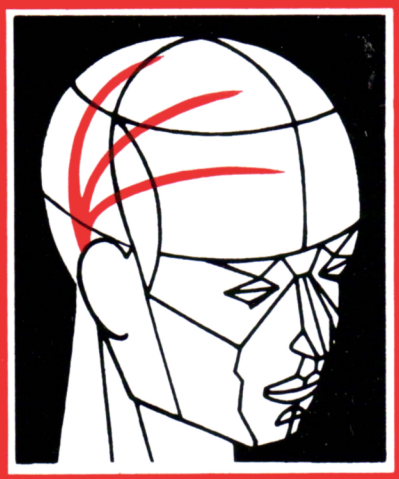
Vascular headaches
of the migraine type

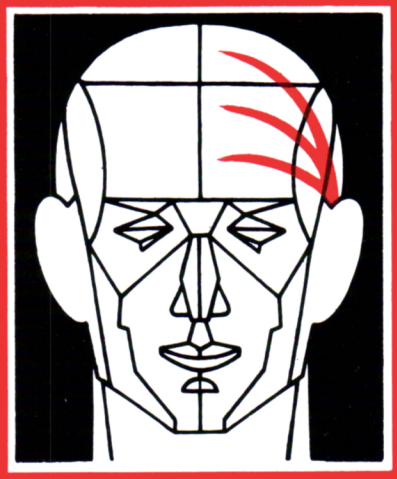
℗ CAFERGOT® tablets
℗ GYNERGEN® tablets and injections

Symptomatic treatment of classic, common, or cluster migraine.



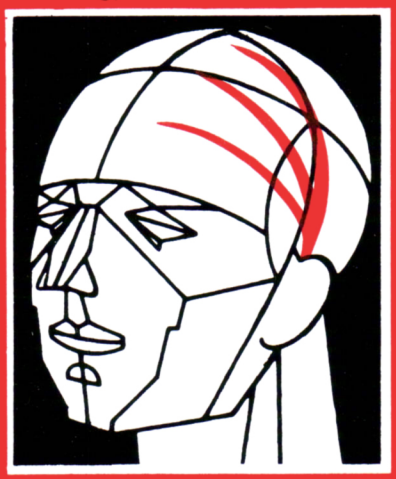
℗ SANDOMIGRAN® tablets
℗ SANSERT® tablets

Prophylactic treatment of frequent, recurring vascular headaches.



© CAFERGOT®-PB tablets and suppositories

Symptomatic treatment of classic, common, or cluster migraine (accompanied by nervous tension, nausea and vomiting).



Tension headaches
(muscle contraction)

© FIORINAL® tablets and capsules
Ⓝ FIORINAL®-C ¼ capsules
Ⓝ FIORINAL®-C ½ capsules

Symptomatic treatment of muscle contraction headache (tension headache).

Other non-vascular headaches

© FIORINAL® tablets and capsules
Ⓝ FIORINAL®-C ¼ capsules
Ⓝ FIORINAL®-C ½ capsules

Symptomatic treatment of other non-vascular headaches (headaches associated with dysmenorrhea, sinusitis, febrile diseases, cold and grippe, overeating, hangover).

Full product information is available upon request.

Contact your Sandoz representative or write to the Medical Services Department of Sandoz (Canada) Limited for a complimentary supply of our new diagnostic aid - the patient's "HEADACHE HISTORY" or for information about our audio visuals concerning the diagnosis and treatment of headaches.

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