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- may be of greater benefit to some patients than the carbidopa/levodopa combination.²
- may provide a more optimal therapeutic response than levodopa alone.²

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Rx Summary

Indications

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Contraindications

Known hypersensitivity to levodopa and/or benserazide. In patients in whom sympathomimetic amines are contraindicated; in conjunction with monoamine oxidase inhibitors or within two weeks of their withdrawal. Clinical or laboratory evidence of uncompensated cardiovascular, endocrine, renal, hepatic, hematologic or pulmonary disease; narrow-angle glaucoma (may be used in wide-angle glaucoma provided intraocular pressure remains under control). History of melanoma or suspicious undiagnosed skin lesions.

Warnings

Discontinue levodopa therapy at least 12 hours before initiating 'Prolopa' therapy. Increase dosage of 'Prolopa' 100-25 gradually to avoid inducing CNS side effects (abnormal movements). Observe patients for signs of depression with suicidal tendencies or other serious behavioural changes. Caution in patients with history of psychotic disorders or those receiving reserpine, phenothiazines or tricyclic antidepressants.

Administer with care to patients with history of myocardial infarction or who have atrial, nodal or ventricular arrhythmias.

Safety in patients under 18 years has not been established. In women who are or may become pregnant benefits should be weighed against possible hazards to mother and fetus. Should not be given to nursing mothers.

Precautions

Caution in patients with history of convulsive disorders. Upper gastrointestinal hemorrhage possible in patients with history of peptic ulcer.

Normal activity should be resumed gradually to avoid risk of injury.

Administer with caution to patients on antihypertensive medication; discontinue 12 hours before anesthesia. Monitor intraocular pressure in patients with chronic wide-angle glaucoma.

Adverse reactions

Most common are abnormal involuntary movements, usually dose dependent, and may disappear or become tolerable after dosage reduction.

Most serious after prolonged therapy are periodic oscillations in performance (end of dose akinesia, on-off phenomenon and akinesia paradoxa).

Nausea, vomiting, arrhythmias and orthostatic hypotension occur less frequently than with levodopa alone.

Psychiatric disturbances, including mild elation, depression, anxiety, agitation, aggression, hallucinations and delusions have been encountered.

Consult monograph for complete list of reported adverse effects.

Dosage

Recommended initial dose is one capsule 'Prolopa' 100-25 once or twice daily, increased carefully by one capsule every third or fourth day until an optimum therapeutic effect is obtained without dyskinesias. At upper limits of dosage increments should be made slowly at 2 to 4-week intervals.

Optimal dosage for most patients is 4 to 8 capsules of 'Prolopa' 100-25 daily (400-800 mg levodopa) divided into 4 to 6 doses. Most patients require no more than 6 capsules 'Prolopa' 100-25 (600 mg levodopa) per day.

'Prolopa' 200-50 capsules are intended only for maintenance therapy once the optimal dosage has been determined using 'Prolopa' 100-25 capsules. No patients should receive more than 5 to 6 capsules 'Prolopa' 200-50 daily (1000 to 1200 mg levodopa) during the first year of treatment.

For patients previously treated with levodopa discontinue for 12 hours and initiate with 'Prolopa' 100-25 to provide approximately 15% of previous levodopa dosage. The initial daily dose, however, should not exceed 6 capsules 'Prolopa' 100-25 divided into 4 to 6 doses.

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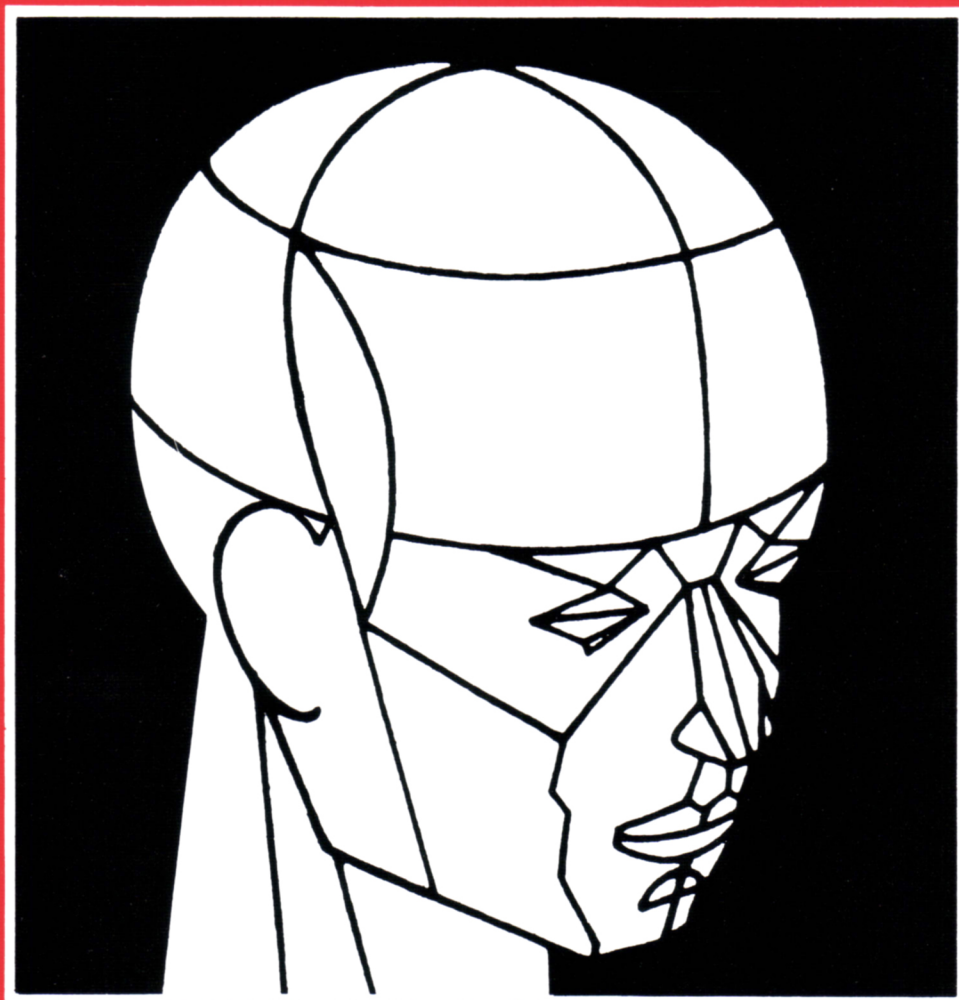
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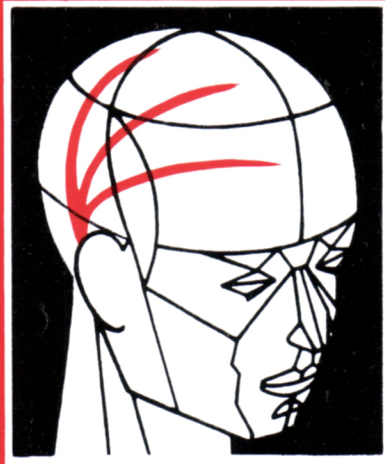
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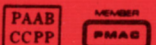
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PRESCRIBING INFORMATION

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.

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