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INDICATIONS: The treatment of Parkinson's syndrome and in the short-term management of drug-induced extrapyramidal symptoms.

CONTRAINDICATIONS: Patients with known hypersensitivity to the drug.

WARNINGS: Patients with a history of epilepsy or other "seizures" should be observed closely for possible untoward central nervous system effects. Patients with a history of congestive heart failure or peripheral ederma should be followed closely as there are patients who developed congestive heart failure while receiving SYMMETREL³. Safety of use in pregnancy has not been established. SYMMETREL³ should not be used in women of childbearing potential, unless the expected benefit to the patient outweighs the possible risk to the fetus.

SYMMETREL® is secreted in the milk and should not be administered to nursing mothers.

PRECAUTIONS: The dose may need careful adjustment in patients with renal impairment, congestive heart failure, peripheral edema or orthostatic hypotension. Since SYMMETREL® is not metabolized and is mainly excreted in the urine, it may accumulate when renal function is inadeouate.

Care should be exercised when administering to patients with liver disease, a history of recurrent eczematoid rash, psychosis, or severe psychoneurosis not controlled by chemotherapeutic agents. Careful observation is required when administered concurrently with central nervous system stimulants.

Patients with Parkinson's syndrome improving on SYMMETREL® should resume normal activities gradually and cautiously, consistent with other medical considerations, such as the presence of osteoporosis or philebothrombosis. Patients receiving SYMMETREL® who note central nervous system effects or blurring of vision should be cautioned against driving or working system effects or blurring of vision should be cautioned against driving or working insituations where alertness is important. SYMMETREL® should not be discontinued abruptly since a few patients with Parkinson's syndrome experienced a parkinsonian crisis, i.e., sudden marked clinical deterioration, when this medication was suddenly stopped.

The dose of anticholinergic drugs or of SYMMETREL® should be reduced if atropine-like effects appear when these drugs are used concurrently.

ADVERSE REACTIONS: Adverse reactions have occurred in patients while receiving SYMMETREL® alone or in combination with anticholinergic antiparkinson drugs and/or levodona.

Important adverse reactions are orthostatic hypotensive episodes, congestive heart failure, depression, psychosis and unnary retention, and rarely convulsions, reversible leukopenia and neutropenia, and abnormal liver function test results.

Adverse reactions of less importance are: anorexia, anxiety, ataxia, confusion, hallucinations, constipation, dizziness (light-headedness), dry mouth, headache, insornnia, livedo reticulairis, nausea, perpheral edema, drowsiness, dyspnea, fatigue, hyperkinesia, irritability, nightmares, rash, slurred speech, visual disturbance, vomiting and weakness; and very rarely eczematolid dermatitis and oculogytic episodes. Some side effects were transient and disappeared even with continued administration of the drug.

SYMPTOMS AND TREATMENT OF OVERDOSAGE: Limited data are available concerning clinical effects and management of SYMMETREL® overdosage. An elderly patient with Parkinson's syndrome who took an overdose of 2.8 g of SYMMETREL® in a suicidal attempt, developed acute toxic psychosis, urinary retention, and a mixed acid-base disturbance. The toxic psychosis was manifested by disorientation, confusion, visual hallucinations and aggressive behaviour. Convulsions did not occur, possibly because the patient had been receiving phenytoin prior to the acute ingesting of SYMMETREL®.

There is no specific antidote. For acute overdosing, general supportive measures should be employed, along with immediate gastric lavage or induction of emesis. Fluids should be forced, and if necessary, given I.V. The pH of the urine has been reported to influence the excretion rate of SYMMETREL[®]. Since the excretion rate of SYMMETREL[®] increases rapidly when the urine is acidic, the administration of urine acidifying fluids may increase the elimination of the drug from the body. Bood pressure, pulse, respiration and temperature should be monitored. The patient should be observed for possible development of arrhythmias, hypotension, hyperactivity, and convolutions; if required, appropriate therapy should be administered. Blood electrolytes, urine pH and urinary output therapy should be monitored. If there is no record of recent voiding, catheterization should be done. The possibility of multiple drug ingestion by the patient should be considered.

DOSAGE AND ADMINISTRATION: Parkinson's Syndrome: Initial dose is 100 mg daily for patients with serious associated medical illnesses or who are receiving high doses of other antiparkinson drugs. After one to several weeks at 100 mg once daily, the dose may be increased to 100 mg twice daily. When JWMETREL² and levodopa are initiated concurrently, SYMMETREL² should be held constant at 100 mg daily or twice daily while the daily dose of levodopa is gradually increased to optimal dose. When used alone, the usual dose of SYMMETREL² is 100 mg twice a day.

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References:

 Schwab RS, Poskanzer DC, England AC Jr., Young RR: Amantadine in Parkinson's disease. JAMA 1972;227:7.

Product monograph available on request.

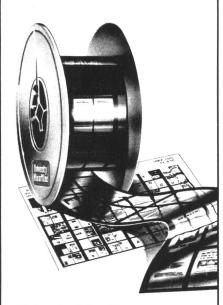
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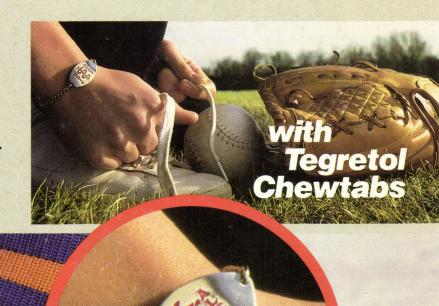


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