For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory xxxxxxx-8883

TIDOMET LS/ TIDOMET PLUS/ TIDOMET FORTE

(Co-Careldopa Tablets B.P.)

Tidomet is a combination of carbidopa, a peripheral decarboxylase inhibitor, with levodopa, a precursor of dopamine, indicated for the treatment of Parkinson's disease. To suit the varied need of patients, Tidomet is marketed in 3 varying strength combinations.

COMPOSITION

Tidomet LS : Each uncoated tablet contains :
Carbidopa B.P. equivalent to Carbidopa anhydrous.....10mg
Levodopa .B.P.....100mg

Tidomet Plus : Each uncoated tablet contains :
Carbidopa B.P. equivalent to Carbidopa anhydrous.....25mg
Levodopa .B.P.....100mg

Tidomet Forte : Each uncoated tablet contains :
Carbidopa B.P. equivalent to Carbidopa anhydrous.....25mg
Levodopa .B.P.....250mg

CLINICAL PHARMACOLOGY

The symptoms of Parkinson's disease are related to depletion of dopamine in the corpus striatum. Administration of dopamine is ineffective in such patients because dopamine does not cross the blood brain barrier. However, levodopa, the precursor, of dopamine, does cross the blood brain barrier and is converted to dopamine in the basal ganglia. When levodopa is administered orally, it is rapidly converted to dopamine in non-neuronal tissues especially intestinal mucosa so that only a small portion of the given dose is transported unchanged to the neuronal tissue. As a consequence large doses of levodopa are required to be administered to produce adequate therapeutic effect which may often be associated with side effects. Combination of levodopa with a selective peripheral decarboxylase inhibitor, carbidopa can almost completely abolish extracerebral metabolism of levodopa and increase availability of levodopa to brain. Pyridoxine hydrochloride (vitamin B_6) in oral doses of 10-25 mg may reverse the effects of levodopa by increasing the rate of decarboxylation. Carbidopa inhibits this action of pyridoxine.

INDICATIONS

Symptoms of idiopathic Parkinson's disease (paralysis agitans), postencephalitic parkinsonism, which may follow injury to the nervous system by carbon monoxide intoxication and manganese intoxication.

CONTRAINDICATIONS

Known hypersensitivity to any of the components, narrow angle glaucoma, patients with suspicious undiagnosed skin lesions or a history of melanoma. MAO inhibitors must be discontinued atleast 2 weeks prior to initiating therapy because of likelihood of development of high blood pressure if both the drugs are given concomitantly.

PRECAUTIONS

Patients receiving levodopa alone must discontinue medication atleast 8 hours before Tidomet is started. Tidomet should be substituted at a dosage that will provide approximately 25% of the previous levodopa dosage. Patients who are taking Tidomet should be instructed not to take additional levodopa unless prescribed by the physician. As with levodopa, Tidomet may cause involuntary movements and mental disturbances. All patients taking Tidomet should be observed carefully for the development of depression with concomitant suicidal tendencies. Tidomet should be administered cautiously to patients with severe cardiovascular or pulmonary disease, bronchial asthma, renal hepatic or endocrine disease, past or current psychosis.

Use In Pregnancy, Nursing Mothers And Children

Tidomet must be used in women of child-bearing age group after weighing the possible hazards to the mother and the child. Tidomet should not be given to nursing mothers.

Safety in patients under 18 years of age has not been established.

ADVERSE REACTIONS

Serious adverse reactions are choreiform, dystonic and other involuntary movements, mental changes including paranoid ideation psychotic episodes, depression with/without development of suicidal tendencies and dementia. The less common and less serious side effects are nausea, orthostatic hypotension, bradykinetic episodes, anorexia, vomiting and dizziness. Rarely GI bleeding, duodenal ulcer, hypertension, etc. have occurred.

DRUG INTERACTIONS

Symptomatic postural hypotension may occur, if Tidomet is added to the treatment of patient receiving antihypertensive drugs. Hypertension and dyskinesia results from the concomitant use of tricyclics and Tidomet. Phenothiazines and butyrophenones may reduce the therapeutic effects of levodopa. Phenytoin and papverine reverse beneficial effects of levodopa.

DOSAGE AND ADMINISTRATION

Carefully titrate dosage in each patient. Initiate treatment with 1 tablet of Tidomet Plus 3 times a day. Dosage may be increased by 1 tablet a day or every other day as necessary until a dosage of 8 tablets of Tidomet Plus per day is reached. If Tidomet LS is used, initiate with 1 tablet 3 or 4 times a day and increased by 1 tablet every day or every other day until a total of 8 tablets i.e. 2 tablets 4 times a day is reached. Transferring patients from levodopa to Tidomet, levodopa must be discontinued at least before 8 hours. 1/4th of the previous levodopa dosage may be started as Tidomet. Patients taking less than 1500 mg of levodopa per day should be started on one tablet of Tidomet Plus 3-4 times a day. Maintenance therapy should be individualized and adjusted according to the desired therapeutic response. When a greater proportion of carbidopa is required, one tablet of Tidomet Plus may be substituted for each tablet of Tidomet LS. When more levodopa is required Tidomet Forte should be substituted at a dosage of 1 tablet 3 or 4 times a day.If necessary the dosage may be increased by 1/2 or 1 tablet everyday or every other day to a maximum of 8 tablets a day. The occurrence of involuntary movements may require dosage reduction; blepharospasm may be a useful early sign of excess dosage in some patients.

OVERDOSAGE

Pyridoxine is not effective in reversing the actions of Tidomet. General supportive measures should be employed alongwith immediate gastric lavage. Intravenous fluids should be administered judiciously and adequate airway maintained. ECG monitoring should be instituted if patient develops arrhythmias. If required appropriate antiarrhythmics should be administered.

EXPIRY DATE

Do not use later than the date of expiry.

STORAGE

Store below 30^{o}C, protected from light.

PRESENTATION

Tidomet LS : It is available as white to off white, round, flat, uncoated tablets with break line on one side; in strips of 10 tablets.
Tidomet Plus : It is available as white to off white, round, flat, uncoated tablets with break line on one side; in strips of 10 tablets.
Tidomet Forte : It is available as white to off white, round, flat, uncoated tablets with break line on one side; in strips of 10 tablets.

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Manufactured by :
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