AGOG Pharma Ltd.

(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)

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LEAFLET

LCDOPA TABLETS

(Co-careldopa Tablets BP)

Composition:
Each film coated tablet contains:
Levodopa BP ..... 250 mg
Carbidopa BP ..... 25 mg

Clinical Pharmacology:
Combination of carbidopa and levodopa for the treatment of Parkinson's disease and syndrome.
Parkinson's disease is a progressive, neurodegenerative disorder of the extrapyramidal nervous system affecting the mobility and control of the skeletal muscular system. Its characteristic features include resting tremor, rigidity, and bradykinetic movements. Symptomatic treatments, such as levodopa therapies, may permit the patient better mobility.

Levodopa, an aromatic amino acid, is a white, crystalline compound, slightly soluble in water, with a molecular weight of 197.2. It is designated chemically as (—)-L-α-amino-β-(3,4-dihydroxybenzene) propanoic acid. Its empirical formula is C9H11NO4. levodopa, the metabolic precursor of dopamine, does cross the blood-brain barrier, and presumably is converted to dopamine in the brain. Dopamine helps to improve the signs of Parkinson's disease.
Carbidopa, an inhibitor of aromatic amino acid decarboxylation, is a white, crystalline compound, slightly soluble in water, with a molecular weight of 244.3. It is designated chemically as (—)-L-ahydrazino-α-methyl-β-(3,4-dihydroxybenzene) propanoic acid monohydrate. Its empirical formula is C10H14N2O4I12O.
Carbidomide belong to a group of medicine called aromatic amino acid decarboxylase inhibitors. It helps levodopa work more effectively by slowing down the speed at which levodopa is broken down in the body.

Indications:
Idiopathic Parkinson's disease
Post-encephalitic Parkinsonism
Symptomatic Parkinsonism

Dosage & Administration:
Take this medication by mouth with or without food as directed by your doctor, usually 3 to 4 times a day. Taking this medication with food may help to decrease nausea. It is best to avoid a high-protein diet (it decreases the amount of levodopa that your body takes in) during treatment, unless directed otherwise by your doctor.
Separate your dose of this medication by as many hours as possible from any iron supplements or products containing iron (such as multivitamins with minerals) you may take. Iron can reduce the amount of this medication absorbed by the body. Consult your doctor or pharmacist for more details. The dosage is based on your medical condition and response to treatment.

Precautions & Warnings:
As with levodopa, periodic evaluations of hepatic, hematopoietic, cardiovascular, and renal function are recommended during extended therapy.
Patients with chronic wide-angle glaucoma may be treated cautiously with LCDOPA provided the intraocular pressure is well-controlled and the patient is monitored carefully for changes in intraocular pressure during therapy.

Dopaminergic agents, including levodopa, may be associated with somnolence and very rarely episodes of sudden onset of sleep. In some cases, these episodes may occur without awareness or warning during daily activities. Patients must be informed of this and advised to exercise caution while driving or operating machines while being treated with dopaminergic agents, including levodopa. Patients who have experienced somnolence and/or an episode of sudden sleep onset must refrain from driving or operating machines.

Contraindications:
Nonselective monoamine oxidase (MAO) inhibitors are contraindicated for use with LCDOPA. These inhibitors must be discontinued at least two weeks prior to initiating therapy with LCDOPA. LCDOPA may be administered concomitantly with the manufacturer's recommended dose of an MAO inhibitor with selectivity for MAO type B (e.g., selegiline HCl).
LCDOPA is contraindicated in patients with known hypersensitivity to any component of this drug, and in patients with narrow-angle glaucoma.
Because levodopa may activate a malignant melanoma, LCDOPA should not be used in patients with suspicious, undiagnosed skin lesions or a history of melanoma.

Adverse Reaction & Side Effects: Seek immediate medical attention in case of following side effects.
Skin: rash, increased sweating, alopecia, dark sweat.
Nervous System/Psychiatric: psychotic episodes including delusions, hallucinations, and paranoid ideation, neuroleptic malignant syndrome, bradykinetic episodes ("on-off" phenomenon), confusion, agitation, dizziness, somnolence, dream abnormalities including nightmares, insomnia, paresthesia, headache, depression with or without development of suicidal tendencies, dementia, pathological gambling, increased libido including hypersexuality, impulse control symptoms.
Cardiovascular: cardiac irregularities, hypotension, orthostatic effects including orthostatic hypotension, hypertension, syncope, phlebitis, palpitation.
Gastrointestinal: dark saliva, gastrointestinal bleeding, development of duodenal ulcer, anorexia, vomiting, diarrhea, constipation, dyspepsia, dry mouth, taste alterations.
Hematologic: agranulocytosis, hemolytic and non-hemolytic anemia, thrombocytopenia, leukopenia. Hypersensitivity: angioedema, urticaria, pruritus, Henoch-Schonlein purpura, bullous lesions (including pemphigus-like reactions).
Musculoskeletal: back pain, shoulder pain, muscle cramps.

STORAGE:
Store under normal storage condition (15°C to 30°C).
Protect from light.
Keep all medicines out of reach of children.

PRASENTATION:
A Bulk pack of 50's Tablets.

Manufactured in India by :
AGOG PHARMA LTD.
Plot No. 33, Sector II, The Vasai Taluka Indl. Co-op. Estate Ltd., Vasai (E), Dist. Thane. INDIA.