

LODOSYN[®]

(CARBIDOPA)

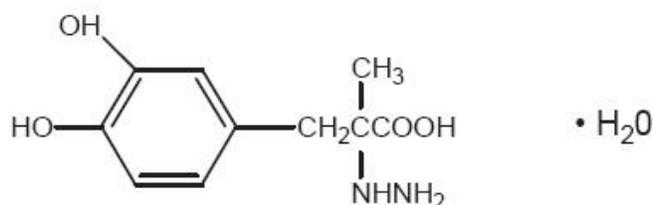
See page 2 carbidopa is not effective in addressing Parkinson's disease symptoms.

TABLETS

When LODOSYN (Carbidopa) is to be given to carbidopa-naive patients who are being treated with levodopa, the two drugs should be given at the same time, starting with no more than 20 to 25% of the previous daily dosage of levodopa when given without LODOSYN (Carbidopa). At least twelve hours should elapse between the last dose of levodopa and initiation of therapy with LODOSYN (Carbidopa) and levodopa. See the WARNINGS and DOSAGE AND ADMINISTRATION sections before initiating therapy.

DESCRIPTION

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- α -hydrazino- α -methyl- β -(3,4-dihydroxybenzene) propanoic acid monohydrate. Its empirical formula is C₁₀H₁₄N₂O₄•H₂O and its structural formula is:



LODOSYN (Carbidopa) tablets contain 25 mg of carbidopa. Inactive ingredients are cellulose, FD&C Yellow 6, magnesium stearate and starch.

Tablet content is expressed in terms of anhydrous carbidopa which has a molecular weight of 226.3.

CLINICAL PHARMACOLOGY

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.

this is beneficial other than in reducing nausea and vomiting, permitting more rapid titration, and providing a somewhat smoother response to levodopa.

Certain patients who responded poorly to levodopa alone have improved when carbidopa and levodopa were given concurrently. This was most likely due to decreased peripheral decarboxylation of levodopa rather than to a primary effect of carbidopa on the peripheral nervous system. Carbidopa has not been shown to enhance the intrinsic efficacy of levodopa.

In deciding whether to give LODOSYN with carbidopa-levodopa or with levodopa to patients who have nausea and/or vomiting, the physician should be aware that, while many patients may be expected to improve, some may not. Since one cannot predict which patients are likely to improve, this can only be determined by a trial of therapy. It should be further noted that in controlled trials comparing carbidopa and levodopa with levodopa alone, about half the patients with nausea and/or vomiting on levodopa alone improved spontaneously despite being retained on the same dose of levodopa during the controlled portion of the trial.

CONTRAINDICATIONS

LODOSYN is contraindicated in patients with known hypersensitivity to any component of this drug.

Nonselective monoamine oxidase (MAO) inhibitors are contraindicated for use with levodopa or carbidopa-levodopa combination products with or without LODOSYN. These inhibitors must be discontinued at least two weeks prior to initiating therapy with levodopa. Carbidopa-levodopa or levodopa may be administered concomitantly with the manufacturer's recommended dose of an MAO inhibitor with selectivity for MAO type B (e.g., selegiline HCl) (see **PRECAUTIONS, Drug Interactions**).

Levodopa or carbidopa-levodopa products, with or without LODOSYN, are contra- indicated in patients with narrow-angle glaucoma.

WARNINGS

LODOSYN (Carbidopa) has no antiparkinsonian effect when given alone. It is indicated for use with carbidopa-levodopa or levodopa. LODOSYN (Carbidopa) does not decrease adverse reactions due to central effects of levodopa.

When LODOSYN (Carbidopa) is to be given to carbidopa-naive patients who are being treated with levodopa alone, the two drugs should be given at the same time.