

CARBIDOPA + LEVODOPA + ENTACAPONE TAB:

Class: Anti-Parkinson's Agent (Decarboxylase Inhibitor with Dopamine Precursor with COMT Inhibitor)

Indications: Anti-Parkinson's

Available dosage form in the hospital: TAB (12.5 MG + 50 MG + 200MG)

TAB (25 MG + 100MG + 200MG)

TAB (37.5 MG + 150MG + 200MG)

Trade Names:

Dosage: Note: All strengths of Stalevo® contain a carbidopa/levodopa ratio of 1:4 plus entacapone 200 mg.

-Parkinson's disease: Oral: Dose should be individualized based on therapeutic response; doses may be adjusted by changing strength or adjusting interval. Fractionated doses are not recommended and only 1 tablet should be given at each dosing interval; maximum daily dose: 8 tablets of Stalevo® 50, 75, 100, 125, or 150, or 6 tablets of Stalevo® 200.

-Patients previously treated with carbidopa/levodopa immediate release tablets (ratio of 1:4):

-With current entacapone therapy: May switch directly to corresponding strength of combination tablet. No data available on transferring patients from controlled release preparations or products with a 1:10 ratio of carbidopa/levodopa.

-Without entacapone therapy:

-If current levodopa dose is >600 mg/day: Levodopa dose reduction may be required when adding entacapone to therapy; therefore, titrate dose using individual products first (carbidopa/levodopa immediate release with a ratio of 1:4 plus entacapone 200 mg); then transfer to combination product once stabilized.

-If current levodopa dose is <600 mg without dyskinesias: May transfer to corresponding dose of combination product; monitor, dose reduction of levodopa may be required.

-Patients previously treated with benserazide/levodopa immediate release tablets (Canadian labeling, not in U.S. labeling):

- With current entacapone therapy: Prior to switching to combination product (carbidopa/levodopa/entacapone), withhold treatment for 1 night, then initiate (carbidopa/levodopa/entacapone) therapy the following morning at a dose that provides either an equivalent amount or ~5% to 10% more levodopa.

Renal Impairment:

No dosage adjustment provided in manufacturer's labeling (has not been studied); use caution with severe renal impairment.

Hepatic Impairment:

No dosage adjustment provided in manufacturer's labeling (has not been studied); use with caution in biliary obstruction or hepatic disease

Common side effect:

Cardiovascular: Arrhythmia, chest pain, edema, flushing, hypotension, hypertension, MI, orthostatic hypotension, palpitation, phlebitis, syncope

Central nervous system: Agitation, anxiety, ataxia, confusion, delusions, dementia, depression (with or without suicidal tendencies), disorientation, dizziness, dreams abnormal, EPS, euphoria, faintness, falling, fatigue, gait abnormalities, headache, hallucinations, impulse control symptoms, insomnia, malaise, memory impairment, mental acuity decreased, nervousness, neuroleptic malignant syndrome, nightmares, on-off phenomena, paranoid ideation, pathological gambling, psychosis, seizure (causal relationship not established), somnolence

Dermatologic: Alopecia, malignant melanoma, rash

Endocrine & metabolic: Hot flashes, hyperglycemia, hypokalemia, libido increased (including hypersexuality), uric acid increased

Gastrointestinal: Abdominal pain, abdominal distress, anorexia, bruxism, constipation, diarrhea, discoloration of saliva, duodenal ulcer, dyspepsia, dysphagia, flatulence, GI bleeding, heartburn, nausea, sialorrhea, taste alterations, tongue burning sensation, weight gain/loss, vomiting, xerostomia

Genitourinary: Discoloration of urine, glycosuria, urinary frequency, priapism, proteinuria, urinary incontinence, urinary retention, urinary tract infection

Hematologic: Agranulocytosis, anemia, Coombs' test abnormal, hematocrit decreased, hemoglobin decreased, hemolytic anemia, leukopenia

Hepatic: Alkaline phosphatase abnormal, ALT abnormal, AST abnormal, bilirubin abnormal, LDH abnormal

Neuromuscular & skeletal: Back pain, dyskinesias (including choreiform, dystonic and other involuntary movements), leg pain, muscle cramps, muscle twitching, numbness, paresthesia, peripheral neuropathy, shoulder pain, tremor increased, trismus, weakness

Ocular: Blepharospasm, blurred vision, diplopia, Horner's syndrome reactivation, mydriasis, oculogyric crises (may be associated with acute dystonic reactions)

Renal: Difficult urination

Respiratory: Cough, dyspnea, hoarseness, pharyngeal pain, upper respiratory infection

Miscellaneous: Discoloration of sweat, diaphoresis increased, hiccups, hypersensitivity reactions (angioedema, pruritus, urticaria, bullous lesions [including pemphigus-like reactions], Henoch-Schönlein purpura [IgA vasculitis])

Pregnancy Risk Factor C