NOVARTIS

STALEVO®

(levodopa/carbidopa/entacapone)

50/12.5/200 mg, 75/18.75/200 mg, 100/25/200 mg, 125/31.25/200 mg,
150/37.5/200 mg and 200/50/200 mg
Film-coated tablets

Basic Succinct Statement

Code: BSS RD 06 MAY 19; APPR 31 MAR 20

This material is only meant for Healthcare Professionals

STALEVO®

Important note: Before prescribing, please consult full prescribing information.

Presentation: Levodopa/carbidopa/entacapone. 50/12.5/200 mg, 75/18.75/200 mg, 100/25/200 mg, 125/31.25/200 mg, 150/37.5/200 mg and 200/50/200 mg film-coated tablets.

Indications: Treatment of patients with idiopathic Parkinson's disease:

1) To substitute (with equivalent strength of each of the three components) for immediate release carbidopa/levodopa and entacapone previously administered as individual products.
2) To replace immediate release carbidopa/levodopa therapy (without entacapone) when patients experience the signs and symptoms of end-of-dose "wearing-off" (only for patients taking a total daily dose of levodopa of 600mg or less and not experiencing dyskinesias, see DOSAGE).

Dosage: ♦Stalevo® is usually used in patients currently treated with corresponding doses of standard release levodopa/DDC inhibitor and entacapone. ♦The daily dose should be optimised using one of the six available tablet strengths. ♦The maximum Stalevo dose for the Stalevo strengths of 50/12.5/200 mg, 75/18.75/200 mg, 100/25/200 mg, 125/31.25/200 mg, and 150/37.5/200 mg is 10 tablets per day; for the 200/50/200 mg strength is 7 tablets per day. ♦Dose adjustment of other antiparkinsonian medicinal products may be necessary when Stalevo treatment is introduced in a patient already not receiving entacapone.

Contraindications: Known hypersensitivity to the active substances or to any of the excipients, severe hepatic impairment, narrow-angle glaucoma, pheochromocytoma, concomitant use with a non-selective monoamine oxidase (MAO-A and MAO-B) inhibitor, concomitant use with a selective MAO-A inhibitor and MAO-B inhibitor, a history of Neuroleptic Malignant Syndrome (NMS) and/or non-traumatic rhabdomyolysis.

Warnings/Precautions: ♦Not recommended for the treatment of drug-induced extrapyramidal symptoms. ♦Caution is recommended when Stalevo is administered to patients with ischemic heart disease, severe cardiovascular or pulmonary disease, bronchial asthma, renal, hepatic or endocrine disease, chronic wide-angle glaucoma, history of peptic ulcer disease, convulsions, myocardial infarction or ventricular arrhythmias, or past or current psychosis, and in the event of general anaesthesia, extended therapy or when discontinuing treatment. ♦Development of mental changes, depression with suicidal tendencies, and other serious antisocial behaviour should be monitored carefully. ♦Follow-up of weight recommended in patients experiencing diarrhoea. Stalevo should be discontinued if prolonged/persistent diarrhoea is suspected to be related to the drug. ♦General medical evaluation including liver function in case of progressive anorexia, asthenia and weight decrease within a relatively short period of time. ♦Development of dopamine dysregulation syndrome (compulsive pattern of dopamine drug misuse) and impulse control disorders (e.g. pathological gambling, increased libido, hypersexuality) should be regularly monitored. ♦Caution in patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency. ♦Stalevo should not be used during pregnancy, unless the benefits for the mother outweigh the possible risks to the foetus, nor

while breast-feeding. ♦Caution when driving or operating machines; patients presenting somnolence and/or sudden sleep onset episodes must refrain from driving and operating machinery. ♦Not recommended in patients under 18 years of age.

Interactions: ♦Symptomatic postural hypotension may occur with concomitant treatment of levodopa with antihypertensives. ♦Caution should be exercised when MAO-A inhibitors, tricyclic antidepressants or noradrenaline reuptake inhibitors are used concomitantly. ♦Stalevo can be used with selegiline (a selective MAO-B inhibitor) but the daily dose of selegiline should not exceed 10 mg. ♦Stalevo should be carefully observed for loss of therapeutic response when co-administered with dopamine receptor antagonists (e.g. some antipsychotics and antiemetics), phenytoin and papaverine. ♦A control of INR is recommended when Stalevo is initiated for patients receiving warfarin. ♦Stalevo and iron preparations should be taken at least 2 to 3 hours apart. ♦Stalevo absorption may be impaired in patients on high protein diet.

Adverse reactions: Haemolytic anaemia, thrombocytopenia, neuroleptic malignant syndrome, rhabdomyolysis, angioedema,hepatitis with mainly cholestatic features, hepatic function test abnormal, ischaemic heart disease, myocardial infarction, irregular heart rhythms, orthostatic hypotension, hypertension, sudden sleep onset episodes, mental impairment (e.g. memory impairment, dementia), anxiety, psychosis, depression with or without suicidal tendencies, dyskinesia, Parkinsonism aggravated, tremor, on and off phenomenon, convulsions, somnolence, dizziness, dystonia, insomnia, hallucinations, confusion, agitation, abnormal dreams, dyspnoea, gastrointestinal haemmorhage, gastrointestinal symptoms (e.g. nausea, vomiting, dyspepsia, abdominal pain, constipation, diarrhoea, dry mouth), dysphagia, weight and appetite decreased, headache, discolouration of urine, skin, hair, sweat and nails, blurred vision, fatigue, asthenia, increased sweating, fall, colitis, dopamine dysregulation syndrome, impulse control disorders (e.g. pathological gambling, increased libido, hypersexuality), rash, urticaria, muscle, musculoskeletal and connective tissue pain, muscle spasms, arthralgia, urinary tract infection, urinary retention, chest pain, peripheral oedema, gait disturbance, malaise.