

## Levodopa And Carbidopa Tablets I.P.

**For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only**

Abbreviated Prescribing information for Levodopa and Carbidopa Tablets I.P.

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

### PHARMACOLOGICAL PROPERTIES:

**MECHANISM OF ACTION:** Levodopa is a precursor of dopamine and is given as replacement therapy in Parkinson's disease. Carbidopa is a peripheral dopa decarboxylase inhibitor. It prevents metabolism of levodopa to dopamine in the peripheral circulation, ensuring that a higher proportion of the dose reaches the brain, where dopamine acts. A lower dose of levodopa can be used, reducing the incidence and severity of side effects.

**INDICATIONS:** Levodopa and Carbidopa tablet is indicated for the symptomatic symptoms of idiopathic Parkinson's Disease.

**DOSAGE AND ADMINISTRATION:** The optimum daily dosage of carbidopa/levodopa must be determined by careful titration in each patient. Carbidopa and Levodopa are available in a ratio of 1:4 or 1:10 of carbidopa to levodopa to provide facility for fine dosage titration for each patient. Tablet should be taken orally.

**CONTRAINDICATION:** Hypersensitivity to the active substance or to any of the excipients of this formulation. Non-selective monoamine oxidase (MAO) inhibitors and selective MAO type A inhibitors are contraindicated for use with Carbidopa and Levodopa. Carbidopa and Levodopa is contraindicated in patients with narrow-angle glaucoma. Since levodopa may activate a malignant melanoma, it should not be used in patients with suspicious undiagnosed skin lesions or a history of melanoma.

**WARNINGS & PRECAUTIONS:** Carbidopa and Levodopa is not recommended for the treatment of drug-induced extrapyramidal reactions. Carbidopa and Levodopa should be administered cautiously to patients with severe cardiovascular or pulmonary disease, bronchial asthma, renal, hepatic or endocrine disease, or history of peptic ulcer disease (because of the possibility of upper gastro-intestinal haemorrhage). Care should be exercised when Carbidopa and Levodopa is administered to patients with a history of myocardial infarction who have residual atrial nodal, or ventricular arrhythmias. Cardiac function should be monitored with particular care in such patients during the period of initial dosage adjustment. Carbidopa and Levodopa should be given cautiously to patients who are taking other medicinal products which may cause orthostatic hypotension. All patients should be monitored carefully for the development of mental changes, depression with suicidal tendencies, and other serious antisocial behavior. Patients with current psychoses should be treated with caution. The occurrence of dyskinesias may require dosage reduction. Therefore, any abrupt dosage reduction or withdrawal of carbidopa/levodopa should be carefully observed, particularly in patients who are also receiving neuroleptics. Dopamine Dysregulation Syndrome (DDS) is an addictive disorder resulting in excessive use of the product seen in some patients treated with carbidopa/levodopa. Before initiation of treatment, patients and caregivers should be warned of the potential risk of developing DDS. Patients should be regularly monitored for the development of impulse control disorders.

**DRUG INTERACTIONS:** Postural hypotension can occur when carbidopa/levodopa is added to the treatment of patients already receiving antihypertensive drugs. Dosage adjustment of the antihypertensive agent may be required. Rarely, reactions including hypertension and dyskinesia have been reported with the concomitant use of tricyclic antidepressants. Anticholinergics may act synergistically with levodopa to decrease tremor. However, combined use may exacerbate abnormal involuntary movements. Concomitant use of COMT (Catechol-O-Methyl Transferase) inhibitors and Carbidopa and Levodopa can increase the bioavailability of levodopa. Dopamine D2 receptor antagonists (e.g. phenothiazines, butyrophenones, and risperidone) and isoniazid, may reduce the therapeutic effects of levodopa. Since levodopa competes with certain amino acids, the absorption of levodopa may be impaired in some patients on a high protein diet.

**ADVERSE REACTIONS:** Urinary tract infections, Leukopenia, haemolytic and non- haemolytic anaemia, thrombocytopenia, Agranulocytosis, Anorexia, Weight gain or loss, Hallucinations, confusion, dizziness, nightmares, sleepiness, fatigue, insomnia, depression with very rare suicide attempts, euphoria, dementia, feeling of stimulation, dream abnormalities, Agitation, fear, reduced thinking capacity, disorientation, headache, increased libido, numbness and convulsions, psychotic episodes including delusions and paranoid ideation, Dopamine dysregulation syndrome, Dyskinesia, chorea, dystonia, extrapyramidal and movement disorders, bradykinetic episodes (the "on- off" phenomenon) may appear some months to years after the beginning of treatment with

levodopa and is probably related to the progression of the disease, the adaptation of dose schedule and dose intervals may be required, Ataxia, increased hand tremor, Malignant neuroleptic syndrome, paraesthesia, falling, walking defects, trismus Levodopa/carbidopa is associated with somnolence and has been associated very rarely with excessive daytime somnolence and sudden sleep onset episodes, Muscle twitch, Blurred vision, blepharospasm, activation of a latent Horner's syndrome, diplopia, dilated pupils, and oculogyric crises, Blepharospasm can be an early sign of overdose, Palpitations, irregular heartbeat, Orthostatic hypotension, inclination to faint, syncope, Hypertension, Phlebitis, Hoarseness, chest pain, Dyspnoea, abnormal breathing pattern, Nausea, vomiting, dry mouth, bitter taste, Constipation, diarrhoea, sialorrhoea, dysphagia, flatulence, Dyspepsia, gastrointestinal pain, dark saliva, bruxism, hiccups, gastrointestinal bleeding, burning sensation of the tongue, duodenal ulceration, Oedema, Angioedema, urticaria, pruritus, facial redness, hair loss, rash, increased sweating, dark sweat and Henoch-Schonlein purpura, Muscle spasms, Dark urine, Urinary retention, urinary incontinence, priapism, Asthenia, weakness, malaise, hot flushes.

**MARKETED BY:**



Torrent Pharmaceuticals Limited.

**IN/ Levodopa And Carbidopa Tablets (100 /25 mg)/ Sep-2025 /01/ABPI**

(Additional information is available on request)