AUSTRALIAN PRODUCT INFORMATION – ORIDOPA 100/25 (levodopa and carbidopa) tablet

1 NAME OF THE MEDICINE

Levodopa and carbidopa (as monohydrate)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

ORIDOPA 100/25 tablets contain levodopa 100 mg and carbidopa (as monohydrate) 25 mg.

For the full list of excipients, see **Section 6.1 List of Excipients**.

3 PHARMACEUTICAL FORM

ORIDOPA 100/25 is supplied as tablets for oral administration.

ORIDOPA 100/25 are white or off-white, round, uncoated tablets debossed with “LC 100” and a score line on one side and plain on the other.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

ORIDOPA 100/25 is indicated for the treatment of Parkinson's disease and syndrome. It is useful in relieving many of the symptoms of parkinsonism, particularly rigidity and bradykinesia.
ORIDOPA 100/25 frequently is helpful in the management of tremor, dysphagia, sialorrhoea and postural instability associated with Parkinson's disease and syndrome.

4.2 DOSE AND METHOD OF ADMINISTRATION

The optimum daily dosage of ORIDOPA 100/25 must be determined by careful titration in each patient. ORIDOPA 100/25 tablets are available in a 1:4 ratio of carbidopa to levodopa.

General considerations
Dosage should be titrated to individual patient needs and this may require adjusting both the individual dose and the frequency of administration.

Studies show that peripheral dopa decarboxylase is saturated by carbidopa at approximately 70 to 100 mg a day. Patients receiving less than this amount of carbidopa are more likely to experience nausea and vomiting.

Standard antiparkinson drugs, other than levodopa alone, may be continued while ORIDOPA 100/25 is being administered, although their dosage may have to be adjusted.

Usual Initial Dosage
Dosage is best initiated with one tablet of ORIDOPA 100/25 three times a day. This dosage schedule provides 75 mg of carbidopa per day. Dosage may be increased by one tablet every day or every other day, as necessary, until a dosage equivalent of eight tablets of ORIDOPA 100/25 a day is reached.

Response has been observed in one day, and sometimes after one dose. Fully effective doses usually are reached within seven days as compared to weeks or months with levodopa alone.

How to Transfer Patients from Levodopa

Because both therapeutic and adverse responses occur more rapidly with ORIDOPA 100/25 than when levodopa is given, patients should be monitored closely during the dose adjustment period. Specifically, involuntary movements will occur more rapidly with ORIDOPA 100/25 than with levodopa. The occurrence of involuntary movements may require dosage reduction. Blepharospasm may be a useful early sign of excess dosage in some patients.

Levodopa should be discontinued at least 12 hours before ORIDOPA 100/25 is started (24 hours for slow-release preparations of levodopa). A daily dosage of ORIDOPA 100/25 should be chosen that will provide approximately 20% of the previous levodopa daily dosage.

Patients who are taking less than 1500 mg of levodopa a day should be started on one tablet of ORIDOPA 100/25 three or four times a day.

Maintenance

Therapy should be individualised and adjusted according to the desired therapeutic response. At least 70 to 100 mg of carbidopa per day should be provided for optimal inhibition of extracerebral decarboxylation of levodopa.

Usual dose is 3 tablets daily. Dosage may be increased by one tablet every day or every other day, as necessary, up to a maximum of 8 tablets daily. Experience with total daily dosages of carbidopa greater than 200 mg is limited. For dosage beyond this recommendation, other brands of levodopa/carbidopa may have to be used. (Patients may require more levodopa but no advantage will be gained by increasing the amount of carbidopa above 200 mg/day).

Adjustment in the dosage of ORIDOPA 100/25 may be necessary.

Patients taking ORIDOPA 100/25 should be instructed not to take additional levodopa unless prescribed.

4.3 CONTRAINDICATIONS

Monoamine oxidase inhibitors (MAOIs) and ORIDOPA 100/25 tablets should not be given concomitantly. MAOIs must be discontinued at least two weeks prior to initiating therapy with ORIDOPA 100/25. ORIDOPA 100/25 may be administered concomitantly with the manufacturer's recommended dose of an MAOI with selectivity for MAO type B, eg selegiline (see Section 4.5 Interactions with Other Medicines and Other Forms of Interactions, Other Drugs).

ORIDOPA 100/25 is contraindicated in patients with known hypersensitivity to any component of this medication and in patients with narrow angle glaucoma.

Because levodopa may activate a malignant melanoma it should not be used in patients with suspicious undiagnosed skin lesions or history of melanoma.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

ORIDOPA 100/25 may be given to patients already receiving levodopa alone; however, the levodopa alone must be discontinued 12 hours before ORIDOPA 100/25 is started. ORIDOPA 100/25 should be substituted at a dosage that will provide approximately 20 percent of the previous levodopa dosage (see Section 4.2 Dose and Method of Administration). Patients taking ORIDOPA 100/25 should be instructed not to take additional levodopa unless prescribed.

ORIDOPA 100/25 is not recommended for the treatment of drug-induced extrapyramidal reactions.

All patients should be monitored carefully for the development of mental changes, depression with suicidal tendencies, or other serious antisocial behaviour.

Dyskinesias may occur in patients previously treated with levodopa alone because carbidopa permits more levodopa to reach the brain and, thus more dopamine to be formed. The occurrence of dyskinesias may require dosage reduction.

Patients with a history of severe involuntary movements or psychotic episodes when treated with levodopa alone should be observed carefully when ORIDOPA 100/25 is substituted. These reactions are thought to be due to increased brain dopamine following administration of levodopa and use of ORIDOPA 100/25 may cause a recurrence.

If concomitant administration of psychoactive drugs is necessary, such drugs should be administered with caution and patients carefully observed for loss of antiparkinsonian effect. Patients with a history of convulsions should be treated with caution.

Levodopa has been associated with somnolence and episodes of sudden sleep onset. Sudden onset of sleep during daily activities, in some cases without awareness or warning signs, has been reported very rarely. Patients must be informed of this and advised to exercise caution while driving or operating machines during treatment with levodopa. Patients who have experienced somnolence and/or an episode of sudden sleep onset must refrain from driving or operating machines. Furthermore, a reduction of dosage or termination of therapy may be considered.

Patients with chronic wide angle glaucoma may be treated cautiously with ORIDOPA 100/25, provided the intraocular pressure is well controlled and the patient monitored carefully for changes in intraocular pressure during therapy.

Care should be exercised in administering ORIDOPA 100/25 to patients who have atrial, nodal or ventricular arrhythmia. In such patients, cardiac function should be monitored continuously during the period of initial dosage adjustment.

Symptomatic postural hypotension has been reported occasionally. For this reason, combination levodopa/carbidopa tablets should be given cautiously to patients on anti-hypertensive drugs. When ORIDOPA 100/25 is started, dosage adjustment of the antihypertensive drug may be required. (For patients receiving pargyline, see Section 4.3 Contraindications, monoamine oxidase inhibitors.)

A symptom complex resembling the neuroleptic malignant syndrome including muscular rigidity, elevated body temperature, mental changes, and increased serum creatine phosphokinase has been reported when antiparkinsonian agents were withdrawn abruptly. Therefore, patients should be

observed carefully when the dosage of ORIDOPA 100/25 is reduced abruptly or discontinued, especially if the patient is receiving neuroleptics.

If general anaesthesia is required, therapy with combination levodopa/carbidopa tablets may be continued as long as the patient is permitted to take fluids and medication by mouth. If therapy is interrupted temporarily, the usual daily dosage may be administered as soon as the patient is able to take oral medication.

ORIDOPA 100/25 should be administered cautiously to patients with severe cardiovascular or pulmonary disease, bronchial asthma, renal, hepatic or endocrine disease. Periodic evaluations of hepatic, haematopoietic, cardiovascular and renal function are recommended during extended therapy.

As with levodopa there is a possibility of upper gastrointestinal haemorrhage in patients with a history of peptic ulcer.

Melanoma
Epidemiological studies have shown that patients with Parkinson's disease have a higher risk (2- to approximately 6-fold higher) of developing melanoma than the general population. Whether the increased risk observed was due to Parkinson's disease or other factors, such as drugs used to treat Parkinson's disease, is unclear.

For the reasons stated above, patients and providers are advised to monitor for melanomas frequently and on a regular basis when using ORIDOPA 100/25 for any indication. Ideally, periodic skin examinations should be performed by appropriately qualified individuals (e.g. dermatologists).

Compulsive behaviour
Patients should be regularly monitored for the development of impulse control disorders. Patients and caregivers should be made aware that behavioural symptoms of impulse control disorders (such as pathological gambling, hypersexuality, increased libido, compulsive spending/buying, and binge/compulsive eating, medication use and punding (repetitive purposeless activity)) have been reported in patients treated with dopamine agonists and/or other dopaminergic treatment for Parkinson's disease, especially at high doses. Review of treatment is recommended if such symptoms develop. Prescribers, patients and caregivers should be alert to the possibility of such behaviour, which may have serious financial and social consequences.

Use in hepatic impairment

ORIDOPA 100/25 should be administered cautiously to patients with hepatic disease. Periodic evaluation of hepatic function is recommended during extended therapy.

Use in renal impairment

ORIDOPA 100/25 should be administered cautiously to patients with renal disease. Periodic evaluation of renal function is recommended during extended therapy.

Use in the elderly

There is wide experience in the use of levodopa and carbidopa in elderly patients. The recommendations set out above reflect the clinical data derived from this experience (see section 4.2 Dose and method of administration).

Paediatric use

Safety and effectiveness of combination levodopa/carbidopa tablets in infants and children have not been established, and its use in patients below the age of 18 is not recommended.

Effects on laboratory tests

Abnormalities in laboratory tests may include elevations of blood urea nitrogen, creatinine, SGOT (AST), SGPT (ALT), lactic dehydrogenase (LDH), bilirubin, alkaline phosphatase or protein bound iodine. More commonly, levels of blood urea nitrogen and uric acid are lower during the administration of combination levodopa/carbidopa tablets than with levodopa.

Decreased haemoglobin and haematocrit; elevated serum glucose, and white blood cells, bacteria and blood in the urine have been reported.

Levodopa-carbidopa preparations may cause a false positive reaction for urinary ketone bodies when a test tape is used for determination of ketonuria. This reaction will not be altered by boiling the urine specimen. False-negative tests may result with the use of glucose-oxidase methods of testing for glycosuria.

Positive Coombs' tests have been reported both with combination levodopa/carbidopa tablets and with levodopa alone, but haemolytic anaemia is rare.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Caution should be exercised when the following drugs are administered concomitantly with ORIDOPA 100/25:

Antihypertensive agents
Symptomatic postural hypotension has occurred when combination levodopa/carbidopa tablets are added to the treatment of patients receiving some antihypertensive drugs. Therefore, when therapy with ORIDOPA 100/25 is started, dosage adjustment of the antihypertensive drug may be required.

Antidepressants
For patients receiving monoamine oxidase inhibitors, see Section 4.3 Contraindications.

There have been rare reports of adverse reactions, including hypertension and dyskinesia, resulting from the concomitant use of tricyclic antidepressants and combination levodopa/carbidopa tablets.

Iron
Studies demonstrate a decrease in the bioavailability of carbidopa and/or levodopa when it is ingested with ferrous sulfate or ferrous gluconate.

Other drugs

Dopamine D2 receptor antagonists (eg., phenothiazines, butyrophenones and risperidone) and isoniazid may reduce the therapeutic effects of levodopa. The beneficial effects of levodopa in Parkinson's disease have been reported to be reversed by phenytoin and papaverine. Patients taking these drugs with ORIDOPA 100/25 should be observed carefully for loss of therapeutic response.

Use of ORIDOPA 100/25 with dopamine-depleting agents (e.g., reserpine and tetrabenazine) or other drugs known to deplete monoamine stores is not recommended.

Concomitant therapy with selegiline and carbidopa-levodopa may be associated with severe orthostatic hypotension not attributable to carbidopa-levodopa alone (see Section 4.3 Contraindications).

Since levodopa competes with certain amino acids the absorption of levodopa may be impaired in some patients on a high protein diet.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

In reproduction studies with levodopa and carbidopa, no effects on fertility were found in rats receiving doses of approximately two times the maximum daily human dose of carbidopa and four times the maximum daily human dose of levodopa.

Therefore, the use of ORIDOPA 100/25 in women of childbearing potential requires that the anticipated benefits of the drug be weighed against possible hazards should pregnancy occur.

Use in pregnancy (Category B3)

Although the effect of combination levodopa/carbidopa tablets on human pregnancy is unknown, levodopa caused visceral and skeletal malformations in rabbits at doses of 125 and 250 mg/kg/day. With combinations of levodopa and carbidopa in doses ranging from 250/50 to 500/100 mg/kg/day there was no evidence of teratogenicity in mice, but in rabbits visceral and skeletal malformations occurred similar to those seen with levodopa alone. Carbidopa alone showed no evidence of teratogenicity in mice and rabbits at doses up to 120 mg/kg/day.

Use in lactation.

It is not known whether carbidopa is excreted in human milk. In a study of one nursing mother with Parkinson's disease, excretion of levodopa in human breast milk was reported. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in infants, combination levodopa/carbidopa tablets should not be used in nursing mothers. A decision should be made either to discontinue nursing or discontinue ORIDOPA 100/25.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Patients being treated with levodopa and presenting with somnolence and/or sudden sleep episodes must be informed to refrain from driving or engaging in activities where impaired alertness may put themselves or others at risk of serious injury or death (e.g. operating machines) until such recurrent episodes and somnolence have resolved. See Section 4.4 Special Warnings and Precautions for Use.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Side effects that occur frequently in patients receiving combination levodopa/carbidopa tablets are those due to the central neuropharmacologic activity of dopamine. These reactions usually can be diminished by dosage reduction. The most common side effects are dyskinesias, including choreiform, dystonic, and other involuntary movements. Muscle twitching and blepharospasm may be taken as early signs to consider dosage reduction.

Other serious side effects are: mental changes, including paranoid ideation and psychotic episodes including delusions, hallucinations; depression with or without development of suicidal tendencies; and dementia. A common but less serious side effect is nausea.

Less frequent side effects are cardiac irregularities and/or palpitation, orthostatic effects including hypotensive episodes, bradykinetic episodes (the "on-off" phenomenon), anorexia, vomiting, dizziness, and somnolence.

Gastrointestinal bleeding, development of duodenal ulcer, hypertension, phlebitis, leucopoenia, haemolytic and non-haemolytic anaemia, thrombocytopenia, agranulocytosis, chest pain, dyspnoea, and paraesthesia have occurred rarely.

Rarely convulsions have occurred; however, a causal relationship with combination levodopa/carbidopa tablets has not been established.

Haemolytic anaemia is extremely rare.

Other side effects that have been reported include:

Body as a whole:	syncope.
Nervous system:	ataxia, numbness, increased hand tremor, muscle twitching, muscle cramps, trismus, activation of latent Horner's syndrome, oculogyric crises, peripheral neuropathy.
Psychiatric:	confusion, insomnia, nightmares and dream abnormalities, hallucinations, delusions, agitation, anxiety, euphoria, lethargy, sedation, increased libido. Levodopa is associated with somnolence and has been associated very rarely with excessive daytime somnolence and sudden sleep onset episodes.
Gastrointestinal:	dry mouth, bitter taste, sialorrhoea, dysphagia, bruxism, hiccups, epigastric and abdominal pain and distress, constipation, diarrhoea, flatulence, burning sensation of the tongue, difficulty in swallowing, dark saliva.
Hypersensitivity:	angioedema, urticaria, pruritus, Henoch-Schönlein purpura.
Investigations:	weight gain, weight loss.
Metabolism and nutrition disorders:	oedema, anorexia.
Integumentary:	flushing, increased sweating, dark sweat, rash, hair loss, bad odour.

Genitourinary:	urinary retention, urinary incontinence, dark urine, priapism, haematuria, urinary tract infection.
Special senses:	diplopia, blurred vision, dilated pupils.
Miscellaneous:	weakness, faintness, fatigue, headache, hoarseness, malaise, hot flushes, sense of stimulation, bizarre breathing patterns, neuroleptic malignant syndrome (see Section 4.4 Special Warnings and Precautions for Use), malignant melanoma (see Section 4.3 Contraindications).

Other side effects that have been reported with controlled release levodopa/carbidopa formulations, and may therefore be potential side effects with immediate release formulations such as ORIDOPA 100/25, are:

Gastrointestinal:	dyspepsia.
Nervous system /psychiatric:	asthenia, decreased mental acuity, disorientation, falling, gait abnormalities.

Post-marketing Data
In post-marketing use, pathological (compulsive) gambling, increased libido, hypersexuality, compulsive spending/buying, and binge/compulsive eating have been reported with dopamine agonists and/or other dopaminergic treatments, and in patients treated with levodopa, including combination levodopa/carbidopa tablets (see Section 4.4 Special Warnings and Precautions for Use).

Reporting suspected adverse effects
Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Management of acute overdosage with combination levodopa/carbidopa tablets is basically the same as management of acute overdosage with levodopa; however, pyridoxine is not effective in reversing the actions of combination levodopa/carbidopa tablets.

In the event of overdosage, general supportive measures should be employed. Intravenous fluids should be administered judiciously, and an adequate airway maintained. Electrocardiographic monitoring should be instituted, and the patient observed carefully for the development of arrhythmias; if required, appropriate antiarrhythmic therapy should be given. The possibility that the patient may have taken other drugs as well as combination levodopa/carbidopa tablets should be taken into consideration. To date, no experience has been reported with dialysis, hence its value in overdosage is not known.

For information on the management of overdose, contact the Poisons Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Symptoms of Parkinson's disease have been related to depletion of dopamine in the corpus striatum of the brain. Levodopa, the metabolic precursor of dopamine, relieves the symptoms of Parkinson's disease presumably by being converted to dopamine in the brain.

Following oral administration, levodopa is rapidly decarboxylated and converted to dopamine in extracerebral tissues and only a small amount of unchanged levodopa reaches the central nervous system. Thus, large doses of levodopa are required at frequent intervals for adequate therapeutic effect and are often attended by many adverse reactions, some of which are attributable to dopamine being formed in extracerebral tissue.

Carbidopa, which does not cross the blood-brain barrier, inhibits only extracerebral decarboxylation of levodopa, making more levodopa available for transport to the brain and conversion to dopamine. The lower dosage reduces or eliminates certain adverse reactions attributable to dopamine being formed in extracerebral tissues.

Following coadministration of levodopa and carbidopa in man, plasma levels of levodopa were markedly increased over those found when the same dosage of levodopa was given alone, while plasma levels of dopamine and homovanillic acid, two principal metabolites of levodopa, were markedly reduced.

Pyridoxine hydrochloride (Vitamin B6) in oral doses of 10 mg to 25 mg has been noted to rapidly reverse the antiparkinsonian effect of levodopa. Carbidopa prevents this action of pyridoxine. In a study in which patients received 100 mg - 500 mg of pyridoxine a day whilst being treated with levodopa and carbidopa in combination, there was no reversal of therapeutic effect.

Clinical trials

Not applicable.

5.2 PHARMACOKINETIC PROPERTIES

Carbidopa

Absorption

Following an oral dose of radioactive labelled carbidopa to healthy subjects and to patients with Parkinson's disease, maximum plasma levels of radioactivity were reached in two to four hours in the subjects and in one and one-half to five hours in the patients.

Metabolism and Excretion

Following an oral dose of radioactive labelled carbidopa to healthy subjects and to patients with Parkinson's disease, approximately equal quantities were excreted in the urine and the faeces by both groups. Comparison of urinary metabolites in healthy subjects and patients indicated that the drug is metabolised to the same degree in both. Urinary excretion of unchanged drug was essentially

complete in seven hours and represented 35 percent of the total urinary radioactivity. Only metabolites were present thereafter.

Among the metabolites excreted by man are α-methyl-3-methoxy-4-hydroxy-phenylpropionic acid and α-methyl-3,4 dihydroxyphenylpropionic acid. These accounted for approximately 14 and 10 percent, respectively, of the radioactive metabolites excreted. Two minor metabolites were found. One was identified as 3,4 dihydroxyphenylacetone and the other tentatively identified as N-methylcarbidopa. They each accounted for less than five percent of the urinary metabolites. Unchanged carbidopa is also present in the urine. No conjugates were found.

Levodopa

Absorption

Levodopa is rapidly absorbed from the gastro-intestinal tract.

Metabolism and Excretion

Levodopa is extensively metabolised. Although more than 30 metabolites may be formed, it is converted mainly to dopamine and in lesser amounts, to adrenaline and noradrenaline. These are ultimately metabolised to the principal excretion products, dopacetic acid, homovanillic acid and vanillylmandelic acid.

When single test doses of radioactive levodopa are given to fasting patients with Parkinson's disease, plasma levels of radioactivity peak in one-half to two hours and remain measurable for four to six hours. At peak levels, about 30 percent of the radioactivity appears as catecholamines, 15 percent as dopamine and 10 percent as dopa.

Radioactive compounds are rapidly excreted in the urine, one-third of the dose appearing in two hours. Eighty to ninety percent of urinary metabolites are phenylcarboxylic acids, principally homovanillic acid. Over 24 hours, one to two percent of recovered radioactivity is dopamine and less than one percent is adrenaline, noradrenaline and unchanged levodopa.

Effect of carbidopa on levodopa metabolism

Carbidopa consistently increased plasma levels of levodopa by statistically significant amounts, as measured against placebo, in healthy subjects. This has been demonstrated when carbidopa is given before levodopa and when the two drugs are given simultaneously. In one study, pretreatment with carbidopa increased plasma levels of a single dose of levodopa about five times and extended the duration of measurable plasma concentrations of levodopa from four hours to eight hours. When the two drugs were given simultaneously in other studies, similar results were obtained.

In a study in which a single dose of stem-labelled levodopa was given to patients with Parkinson's disease who had been pretreated with carbidopa, there was an increase in the half-life of total plasma radioactivity derived from the levodopa from 3 hours to 15 hours. The proportion of radioactivity remaining as unmetabolised levodopa was increased at least three times by carbidopa. Plasma and urinary dopamine and homovanillic acid were both decreased by carbidopa pretreatment.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

In a two-year bioassay with levodopa and carbidopa, no evidence of carcinogenicity was found in rats receiving doses of approximately two times the maximum daily human dose of carbidopa and four times the maximum daily human dose of levodopa.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

In addition to the active ingredients, carbidopa and levodopa, each tablet contains the following inactive ingredients: maize starch, mannitol, croscarmellose sodium, povidone and magnesium stearate.

6.2 INCOMPATIBILITIES

Not applicable.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C. Keep in original container. Protect from light.

6.5 NATURE AND CONTENTS OF CONTAINER

Container: HDPE bottles with a PP child resistant closure. Pack size: 100 tablets

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

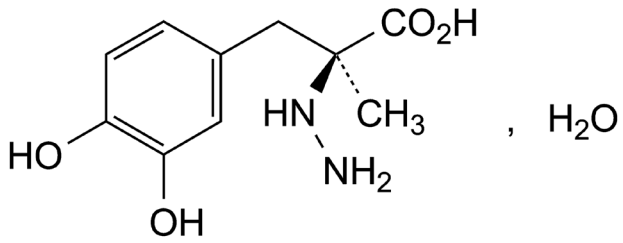
In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

Carbidopa

Carbidopa, an inhibitor of aromatic amino acid decarboxylase, is a white, crystalline compound, slightly soluble in water. It is designated chemically as (-)-L-alpha-hydrazino-alpha-methyl-beta-(3,4-dihydroxy-benzene) propanoic acid monohydrate. Tablet content is expressed in terms of anhydrous carbidopa.

Chemical structure



Molecular formula and weight

$C_{10}H_{14}N_2O_4.H_2O$ 244.3

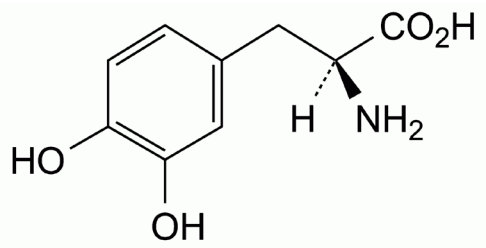
CAS number

38821-49-7

Levodopa

Levodopa, an aromatic amino acid, is a white, crystalline compound, slightly soluble in water. It is designated chemically as (-)-L-alpha-amino-beta-(3,4-dihydroxybenzene) propanoic acid.

Chemical structure



Molecular formula and weight

$C_9H_{11}NO_4$ 197.2

CAS number

59-92-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

S4 – Prescription Only Medicine

8 SPONSOR

Orion Pharma (Aus) Pty Limited
Level 24, Tower 3, 300 Barangaroo Avenue
Sydney NSW 2000, Australia
Telephone: 1800 861 913

9 DATE OF FIRST APPROVAL

16 September 2024.

10 DATE OF REVISION

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information