Cinemet® CR | Cinemet® CR Half

Levodopa + Carbidopa

Description

Cinemet® CR is a combination of Levodopa and Carbidopa in a controlled release tablet formulation for the treatment of Parkinson's disease. Levodopa, the metabolic precursor of dopamine, crosses the blood-brain barrier and is converted to dopamine in the brain. Carbidopa is a dopa decarboxylase (DDC) inhibitor which reduces the peripheral metabolism of Levodopa to dopamine, and thus, more Levodopa becomes available to the brain.

Indication & usage

Cinemet® CR is indicated for-

- Idiopathic Parkinson's disease.
- Postencephalitic parkinsonism.
- Symptomatic parkinsonism (carbon monoxide or manganese intoxication).
- Patients with Parkinson's disease or parkinsonism who are taking vitamin preparations that contain pyridoxine.
- To reduce "off" time in patients previously treated with Levodopa/decarboxylase inhibitor preparations, or with Levodopa alone, who have had motor fluctuations characterized by end-of-dose deterioration ("wearing-off" phenomenon), peak dose dyskinesia, akinesia, or similar evidence of short-duration motor disturbances.

Dosage and administration

Parkinson's disease

Cinemet® CR tablets contain 4:1 ratio of Levodopa to Carbidopa. Cinemet® CR contains Levodopa 200 mg & Carbidopa 50 mg in each tablet and Cinemet® CR Half contains Levodopa 100 mg & Carbidopa 25 mg in each tablet. The daily dose of Cinemet® CR must be determined by careful titration.

Initial dosage

Patients who have not received prior Levodopa therapy

In early stage patients who have not had prior Levodopa therapy, the initial recommended dose is one tablet of Cinemet® CR daily. Initial dosages should not be given at intervals of less than 6 hours.

Patients currently treated with Levodopa alone

Levodopa must be discontinued at least eight hours before starting the therapy with Cinemet® CR. In patients with mild to moderate disease, the initial recommended dose is 1 tablet of Cinemet® CR two or three times daily.

Patients currently treated with conventional Levodopa-Carbidopa combination

A guide for substitution of Cinemet® CR treatment for conventional Levodopa-Carbidopa combination is shown in the table below:

Guidelines for initial conversion from conventional Levodopa-Carbidopa combination to Cinemet® CR:

Conventional dosage form (total daily dose of Levodopa in mg)	Levodopa and Carbidopa controlled release tablets *(total daily dose of Levodopa in mg)*	Cinemet® CR Dosage Regimen
300 - 400	400	1 tablet of Cinemet® CR twice daily
500 - 600	600	1 tablet of Cinemet® CR thrice daily
700 - 800	800	4 tablets of Cinemet® CR in 3 or more divided doses
900 - 1000	1000	5 tablets of Cinemet® CR in 3 or more divided doses
1100-1200	1200	6 tablets of Cinemet® CR in 3 or more divided doses
1300-1400	1400	7 tablets of Cinemet® CR in 3 or more divided doses
1500-1600	1600	8 tablets of Cinemet® CR in 3 or more divided doses
Cinemet® CR Half tablet is available to facilitate titration when 100 mg steps are required		

Titration

Following initiation of therapy, doses and dosing intervals may be increased or decreased, depending upon therapeutic response. Most patients have been adequately treated with dosage of Cinemet® CR that provide 400 mg to 1600 mg per day. Higher doses of Cinemet® CR (2400 mg or more of Levodopa per day) and shorter intervals (less than 4 hours) have been used, but are not usually recommended. When doses of Cinemet® CR are given at intervals of less than 4 hours, or if the divided doses are not equal, it is recommended that the smaller doses may be given at the end of the day.

Maintenance

Because Parkinson's disease is progressive, periodic clinical evaluations are recommended. Adjustment of the dosage regimen of Cinemet® CR may be required.

Addition of other Anti-Parkinson medications

Anticholinergic agents, dopamine agonists and Amantadine can be given with Cinemet® CR. Dosage adjustment of Cinemet® CR may be necessary when these agents are added.

Interruption of therapy

Patients should be observed carefully if abrupt reduction or discontinuation of Cinemet® CR is required; especially if the patient is receiving neuroleptics. If general anesthesia is required, Cinemet® CR may be continued as long as the patient is permitted to take oral medication.

Use in pregnancy and lactation

Pregnancy category C. During pregnancy & nursing Levodopa-Carbidopa combination should not be given.

Use in children

Use of Levodopa-Carbidopa combination in patients below the age of 18 is not recommended.

Hepatic and renally impaired patients

Should be administered cautiously to patients with severe hepatic & renal disease.

Side effects

The most common side effects of Levodopa and Carbidopa controlled release tablet are dyskinesia, nausea, hallucinations, confusion, dizziness, chorea and dry mouth. The uncommon side effects are dream abnormalities and sudden sleep onset episodes, dystonia, asthenia, agitation, anxiety, headache, extrapyramidal and movement disorders, insomnia, vomiting, constipation, diarrhoea, dyspepsia and anorexia.

Precautions

Patients with chronic wide-angle glaucoma may be treated cautiously. Dopaminergic agents, including Levodopa may be associated with somnolence and very rarely episodes of sudden onset of sleep. Patients must be informed of this and advised to exercise caution while driving or operating machines while being treated with such medications. Patients with Parkinson's disease have a higher risk of developing melanoma. Prescribers are advised to monitor for melanomas frequently and on a regular basis.

Drug interactions

Caution should be exercised when antihypertensive agents, antidepressants (tricyclic antidepressants and monoamine oxidase-A-inhibitors) are administered concomitantly with Levodopa-Carbidopa combination. When therapy with this combination is started, dosage adjustment of the antihypertensive agent may be required. Anticholinergics may affect the absorption of this combination. Antipsychotics 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 Levodopa-Carbidopa combination should be carefully observed for loss of therapeutic response. The absorption of this combination may be impaired in some patients on a high protein diet.

Contraindications

Non-selective monoamine oxidase (MAO) inhibitors are contraindicated for use with Cinemet® CR. Cinemet® CR may be administered concomitantly with the manufacturer's recommended dose of an MAO inhibitor with selectivity for MAO type B (e.g. Selegiline HCl). Cinemet® CR is contraindicated in patients with known hypersensitivity to any component of this medication, and in patients with narrow-angle glaucoma. Levodopa-Carbidopa combination should not be used in patients with suspicious undiagnosed skin lesions or a history of melanoma.

Overdose

Management of acute overdose with Levodopa-Carbidopa combination is basically the same as management of acute overdose with Levodopa; however, pyridoxine is not effective in reversing the actions of Levodopa-Carbidopa combination. Patient should be observed carefully for the development of arrhythmias; if required, appropriate anti-arrhythmic therapy should be given. The possibility that the patient may have taken other agents as well as this combination should be taken into consideration.

Pharmaceutical precautions

Store in a cool (below 25°C) and dry place. Protect from light.

Presentation

Cinemet® CR tablet : Each controlled release tablet contains Levodopa BP 200 mg & Carbidopa 50 mg as Monohydrate USP.

Cinemet® CR Half tablet : Each controlled release tablet contains Levodopa BP 100 mg & Carbidopa 25 mg as Monohydrate USP.

Package quantities

Cinemet® CR tablet : Carton of 50 tablets in blister pack.

Cinemet® CR Half tablet : Carton of 50 tablets in blister pack.

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