

CLINICAL UPDATE

Brand Name	Dhivy®
Generic Name	carbidopa levodopa
Drug Manufacturer	Riverside Pharma Corp

Clinical Update

TYPE OF CLINICAL UPDATE

Type 5 - New Formulation or New Manufacturer

FDA APPROVAL DATE

November 12, 2021

LAUNCH DATE

November 18, 2021

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Type 5 - New Formulation or New Manufacturer; New Drug Application (NDA): 214869

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION(S) FOR USE

Dhivy® is a combination of carbidopa (an aromatic amino acid decarboxylation inhibitor) and levodopa (an aromatic amino acid) indicated for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and symptomatic parkinsonism that may follow carbon monoxide intoxication or manganese intoxication.

MECHANISMS OF ACTION

Carbidopa

When levodopa is administered orally, it is rapidly decarboxylated to dopamine in extracerebral tissues so that only a small portion of a given dose is transported unchanged to the central nervous system. Carbidopa inhibits the decarboxylation of peripheral levodopa, making more levodopa available for delivery to the brain.

Levodopa

Levodopa is the metabolic precursor of dopamine, does cross the blood-brain barrier, and presumably is converted to dopamine in the brain. This is thought to be the mechanism whereby levodopa treats symptoms of Parkinson's disease.

DOSAGE FORM(S) AND STRENGTH(S)

Tablets: Carbidopa and levodopa 25 mg/100 mg, functionally scored. Each Dhivy® tablet has 3 functional scores with each segment containing 6.25 mg of carbidopa and 25 mg of levodopa.

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DOSE & ADMINISTRATION

- The recommended starting dosage of Dhivy® is one 25 mg /100 mg tablet taken orally three times a day.
- Dosage may be increased by up to one whole tablet every day or every other day, as needed, until a maximum dosage of eight whole tablets of Dhivy® a day is reached.

EFFICACY

The efficacy of Dhivy® is based upon bioavailability studies comparing Dhivy® to an immediate-release tablet containing 25 mg of carbidopa and 100 mg of levodopa.

Following single oral administration of a Dhivy® tablet, Dhivy® was shown to be bioequivalent to an immediate-release carbidopa/levodopa 25/100 mg tablet under fasting conditions for both carbidopa and levodopa.