



Dhivy™ (carbidopa/levodopa) – New drug approval

- On November 12, 2021, the [FDA approved](#) Riverside Pharmaceutical's [Dhivy \(carbidopa/levodopa\)](#) tablets, for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and symptomatic parkinsonism that may follow carbon monoxide intoxication or manganese intoxication.
- Carbidopa/levodopa is already available generically as an oral immediate-release tablet, immediate-release disintegrating tablet, and extended-release tablet.
- 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.
- Dhivy is contraindicated in patients:
 - Currently taking a nonselective monoamine oxidase (MAO) inhibitor or have recently (within 2 weeks) taken a nonselective MAO inhibitor.
 - With known hypersensitivity to any component of Dhivy.
- Warnings and precautions for Dhivy include falling asleep during activities of daily living and somnolence; withdrawal-emergent hyperpyrexia and confusion; cardiovascular ischemic events; hallucinations/psychotic-like behavior; impulse control/compulsive behaviors; dyskinesia; peptic ulcer disease; glaucoma; laboratory tests; and depression/suicidality.
- The most common adverse reactions reported with carbidopa/levodopa tablets have included dyskinesias, such as choreiform, dystonic, and other involuntary movements, and nausea.
- The recommended starting dosage of Dhivy is one 25 mg/100 mg tablet taken orally three times a day. This dosage schedule provides 75 mg of carbidopa per day. Dosage may be increased by up to one whole tablet every day or every other day, as needed to a maximum daily dosage of eight whole tablets.
 - Dosing with Dhivy should be individualized and adjusted according to clinical response and tolerability.
- Riverside Pharmaceutical's launch plans for Dhivy are pending. Dhivy will be available as a carbidopa and levodopa 25 mg/100 mg tablet, 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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