

Gocovri™ (amantadine) – New drug approval

- On August 24, 2017, [Adamas announced](#) the FDA approval of [Gocovri \(amantadine\)](#) extended-release capsules, for the treatment of dyskinesia in patients with Parkinson's disease (PD) receiving levodopa-based therapy, with or without concomitant dopaminergic medications.
- PD is a chronic neurodegenerative disorder resulting from a loss of dopamine in the brain. PD affects an estimated 1 million Americans.
 - Dyskinesia is a consequence of levodopa-based PD treatment and is characterized by involuntary and non-rhythmic movements that are purposeless and unpredictable.
 - Approximately 150,000 to 200,000 Americans with PD are affected by dyskinesia.
- Gocovri contains amantadine, a weak noncompetitive antagonist of the NMDA receptor. It may exert direct or indirect effects on dopamine neurons.
 - Amantadine is also generically available as immediate-release [capsules](#), [tablets](#), and [oral solution](#). Immediate-release amantadine is indicated for influenza A prophylaxis, influenza A treatment, drug-induced extrapyramidal reactions, and PD.
- The safety and efficacy of Gocovri were based on two placebo-controlled trials in 196 patients with PD. The primary endpoint was the change in the Unified Dyskinesia Rating Scale (UDysRS) score from baseline to week 12.
 - In both trials, greater reduction in dyskinesia was achieved with Gocovri vs. placebo, as measured by the change in UDysRS score (study 1: $p < 0.0009$, study 2: $p < 0.0001$).
- Gocovri is contraindicated in patients with end-stage renal disease (ie, creatinine clearance < 15 mL/min/1.73 m²).
- Warnings and precautions of Gocovri include falling asleep during activities of daily living and somnolence, suicidality and depression, hallucinations/psychotic behavior, dizziness and orthostatic hypotension, withdrawal-emergent hyperpyrexia and confusion, and impulse control/compulsive behavior.
- The most commonly observed adverse reactions (>10 % and greater than placebo) with Gocovri use were hallucination, dizziness, dry mouth, peripheral edema, constipation, fall, and orthostatic hypotension.
- The recommended initial dose of Gocovri is 137 mg orally once daily at bedtime. After 1 week, the dose may be increased to 274 mg (two 137 mg capsules) once daily at bedtime.
 - Gocovri should be swallowed whole and not crushed, chewed, or divided.
 - Gocovri capsules can be opened and sprinkled on a small amount (teaspoonful) of soft food, such as applesauce.
 - It is recommended to avoid sudden discontinuation of Gocovri.

- Adamas plans to launch Gocovri in the 4th quarter of 2017. Gocovri will be available as 68.5 mg and 137 mg capsules.



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