

## Osmolex ER™ (amantadine) – New drug approval

- On February 19, 2018, [Osmotica Pharmaceutical announced](#) the FDA approval of [Osmolex ER \(amantadine\)](#), for the treatment of Parkinson's disease and for the treatment of drug-induced extrapyramidal reactions in adult patients.
- Amantadine is also available generically as immediate-release [capsules](#), [tablets](#), and [oral solution](#), and as extended-release capsules ([Gocovri™](#)).
  - Amantadine capsules, tablets and oral solution are indicated for the prophylaxis and treatment of signs and symptoms of infection caused by various strains of influenza A virus. Amantadine is also indicated in the treatment of Parkinson's disease/syndrome and drug-induced extrapyramidal reactions.
  - Gocovri is indicated for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications.
- Osmolex ER tablets contain amantadine in an extended-release core and an outer immediate-release layer that allows for release of amantadine throughout the day.
- The efficacy of Osmolex ER is based upon bioavailability studies comparing Osmolex ER to immediate-release amantadine.
- Osmolex ER is contraindicated in patients with end-stage renal disease (ie, creatinine clearance below 15 mL/min/1.73 m<sup>2</sup>).
- Warnings and precautions of Osmolex ER 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 behaviors.
- The most common adverse reactions (≥ 5%) with immediate-release amantadine use were nausea, dizziness/lightheadedness, and insomnia.
- The recommended initial dosage of Osmolex ER is 129 mg orally once daily in the morning.
  - The dosage may be increased in weekly intervals to a maximum daily dose of 322 mg (administered as a 129 mg and 193 mg tablet), taken in the morning.
  - Osmolex ER is not interchangeable with other amantadine immediate- or extended-release products.
  - For patients unable to tolerate > 100 mg/day of immediate-release amantadine, there is no equivalent dose or dosing regimen of Osmolex ER.
- Osmotica Pharmaceutical's launch plans for Osmolex ER are pending. Osmolex ER will be available as 129 mg, 193 mg, and 258 mg extended-release tablets.