

## Adzenys ER™ (amphetamine) – New formulation approval

- On September 15, 2017, [Neos Therapeutics announced](#) the FDA approval of [Adzenys ER \(amphetamine\)](#) oral suspension for the treatment of attention deficit hyperactivity disorder (ADHD) in patients 6 years and older.
  - Amphetamine is a Schedule II controlled substance.
- Extended-release amphetamine is also available as [Adzenys XR-ODT® \(amphetamine\)](#) extended-release orally disintegrating tablets and [Dyanavel® XR \(amphetamine\)](#) extended-release oral suspension.
- A pharmacokinetic study demonstrated that a single dose of Adzenys ER provided comparable plasma concentrations to mixed salts of a single-entity amphetamine extended-release capsule product.
- The safety and efficacy of Adzenys ER has been established based on adequate and well-controlled studies of mixed salts of a single-entity amphetamine extended-release capsule product in the treatment of ADHD.
- Similar to other amphetamine products, Adzenys ER contains a boxed warning for abuse and dependence.
- Adzenys ER is contraindicated in patients known to be hypersensitive to amphetamine, or other components of Adzenys ER and in patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs (including MAOIs such as [linezolid](#) or intravenous [methylene blue](#)), because of an increased risk of hypertensive crisis.
- Warnings and precautions of Adzenys ER include serious cardiovascular reactions, blood pressure and heart rate increases, psychiatric events, long-term suppression of growth, peripheral vasculopathy, including Raynaud's phenomenon, serotonin syndrome, potential for overdose due to medication errors, and potential for intestinal necrosis.
- The most common adverse reactions ( $\geq 5\%$ ) with Adzenys ER use in pediatric patients ages 6 to 12 years were loss of appetite, insomnia, abdominal pain, emotional lability, vomiting, nervousness, nausea, and fever.
- The most common adverse reactions ( $\geq 5\%$ ) with Adzenys ER use in pediatric patients ages 13 to 17 years were loss of appetite, insomnia, abdominal pain, weight loss, and nervousness.
- The most common adverse reactions ( $\geq 5\%$ ) with Adzenys ER use in adults were dry mouth, loss of appetite, insomnia, headache, weight loss, nausea, anxiety, agitation, dizziness, tachycardia, diarrhea, asthenia, and urinary tract infections.
- The recommended starting dose for patients 6 to 17 years of age is 6.3 mg (5 mL) once daily in the morning. The dose is increased in increments of 3.1 mg (2.5 mL) or 6.3 mg (5 mL) at weekly intervals. The maximum dose is 18.8 mg (15 mL) daily for patients 6 to 12 years and 12.5 mg (10 mL) daily for patients 13 to 17 years. The recommended dose for adults is 12.5 mg (10 mL) daily.
  - Adzenys ER should be administered orally once daily in the morning with or without food. The dose should be individualized according to the therapeutic needs and response of the patient.

- Shake the bottle of Adzenys ER before administering the dose. Do not add Adzenys ER to food or mix Adzenys ER with other liquids before consuming.
- Neos Therapeutics plans to launch Adzenys ER in early 2018. Adzenys ER oral suspension will be available as a 1.25 mg/mL, 450 mL bottle.



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