Arynta™ (lisdexamfetamine) – New drug approval

- On June 16, 2025, the FDA approved Azurity Pharmaceuticals' Arynta (lisdexamfetamine) oral solution, for the **treatment of attention deficit hyperactivity disorder (ADHD) in adults and pediatric patients 6 years and older and moderate to severe binge eating disorder (BED) in adults**.
    - Pediatric patients with ADHD younger than 6 years of age experienced more long-term weight loss than patients 6 years and older.
    - Arynta is not indicated or recommended for weight loss. Use of other sympathomimetic drugs for weight loss has been associated with serious cardiovascular adverse events. The safety and effectiveness of Arynta for the treatment of obesity have not been established.
- Arynta is the first oral solution formulation of lisdexamfetamine.
    - **Lisdexamfetamine is also available as an oral capsule and chewable tablet** (brand Vyvanse® and generics).
- The efficacy of Arynta has been established based on adequate and well-controlled studies of oral lisdexamfetamine dimesylate in the treatment of adults and pediatric patients 6 years and older with ADHD and adults with moderate to severe BED.
- Arynta carries a boxed warning for **abuse, misuse, and addiction**.
- Arynta is contraindicated in patients with:
    - Known hypersensitivity to amphetamine products or other ingredients of Arynta.
    - Patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs.
- Additional warnings and precautions for Arynta include risks to patients with serious cardiac disease; increased blood pressure and heart rate; psychiatric adverse reactions; long-term suppression of growth in pediatric patients; peripheral vasculopathy, including Raynaud's phenomenon; serotonin syndrome; and motor and verbal tics, and worsening of Tourette's syndrome.
- The most common adverse reactions (≥ 5% and at a rate at least twice placebo) with Arynta use in ADHD patients were anorexia, anxiety, decreased appetite, decreased weight, diarrhea, dizziness, dry mouth, irritability, insomnia, nausea, upper abdominal pain, and vomiting.
- The most common adverse reactions (≥ 5% and at a rate at least twice placebo) in patients with BED were dry mouth, insomnia, decreased appetite, increased heart rate, constipation, feeling jittery, and anxiety.
- The recommended starting dosage of Arynta for ADHD in adults and pediatric patients 6 years and older is 30 mg once daily in the morning. Dosage may be adjusted in increments of 10 mg or 20 mg at approximately weekly intervals up to the maximum recommended dosage of 70 mg once daily.
- The recommended starting dosage of Arynta for BED in adults is 30 mg once daily to be titrated in increments of 20 mg at approximately weekly intervals to achieve the recommended target dose of

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50 mg to 70 mg once daily. The maximum recommended dosage is 70 mg once daily. Arynta should be discontinued if binge eating does not improve.

- Azurity Pharmaceuticals' launch plans for Arynta are pending. Arynta will be available as a 10 mg/mL oral solution.