Xelstrym™ (dextroamphetamine) – New drug approval

- On March 23, 2022, Noven Therapeutics announced the FDA approval of Xelstrym (dextroamphetamine), for the treatment of attention deficit hyperactivity disorder (ADHD) in adults and pediatric patients 6 years and older.
    - Limitation of use: Pediatric patients younger than 6 years of age experienced more long-term weight loss than patients 6 years and older.
    - Xelstrym is a Schedule II controlled substance.
- Xelstrym is the first transdermal patch formulation of amphetamine.
- The efficacy of Xelstrym was established in a randomized, double-blind, placebo-controlled, cross-over design, modified analog classroom study in 110 pediatric patients 6 to 17 years with ADHD. Efficacy was assessed using the Swanson, Kotkin, Agler, M.Flynn, and Pelham (SKAMP) total score, a validated 13-item rating scale assessing manifestations of ADHD in a classroom setting. Efficacy was solely based on data from the first week of the two-week double-blind, placebo-controlled, crossover treatment phase of the study.
    - The least-squares mean SKAMP total score (averaged over classroom day) was 12.4 and 17.1 with Xelstrym and placebo, respectively (placebo-subtracted difference -4.7, 95% CI: -8.0, -1.4).
- In addition to the study above, the efficacy of Xelstrym was also established based on adequate and well-controlled studies of lisdexamfetamine in pediatric and adult patients.
- Xelstrym carries a boxed warning for abuse and dependence.
- Xelstrym is contraindicated in patients:
    - With known hypersensitivity to amphetamine products or other components of Xelstrym.
    - Taking monoamine oxidase inhibitors (MAOI), or within 14 days of stopping MAOIs, because of an increased risk of hypertensive crisis.
- Additional warnings and precautions for Xelstrym include serious cardiovascular reactions; blood pressure and heart rate increases; psychiatric adverse reactions; suppression of growth; peripheral vasculopathy, including Raynaud's phenomenon; serotonin syndrome; contact sensitization; application site reactions; and use of external heat.
- The most common adverse reactions (incidence ≥ 2% and greater than the rate for placebo) in pediatric patients 6 to 17 years with Xelstrym use were decreased appetite, headache, insomnia, tic, abdominal pain, vomiting, nausea, irritability, increased blood pressure, and increased heart rate.
- The most common adverse reactions (incidence ≥ 5% and at a rate at least twice placebo) in adults treated with lisdexamfetamine were decreased appetite, insomnia, dry mouth, diarrhea, nausea, and anxiety.
- The recommended starting dose of Xelstrym in pediatric patients 6 to 17 years is 4.5 mg/9 hours. Dosage may be adjusted in weekly increments of 4.5 mg up to a maximum recommended dose of 18 mg/9 hours.

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- Xelstrym is applied to the application site 2 hours before an effect is needed and remove within 9 hours after application. Dose titration and final dosage should be individualized depending on clinical response and tolerability.

- The recommended starting dose of Xelstrym in adults is 9 mg/9 hours. Dosage may be adjusted up to a maximum recommended dose of 18 mg/9 hours.

- Noven Therapeutics plans to launch Xelstrym as early as the second half of this year. Xelstrym will be available as 4.5 mg/9 hours, 9 mg/9 hours, 13.5 mg/9 hours, and 18 mg/9 hours transdermal systems.

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