Adhansia XR™ (methylphenidate) – New drug approval

- On February 27, 2019, the FDA approved Purdue Pharma's Adhansia XR (methylphenidate) extended-release capsules, for the treatment of attention deficit hyperactivity disorder (ADHD) in patients 6 years and older.
    - Adhansia XR is a Schedule II controlled substance.
- Methylphenidate is also available generically as an extended-release capsule, oral solution, extended-release tablet, chewable tablet, and an immediate release tablet.
    - The oral extended-release capsule is approved for ADHD.
    - The oral solution, extended-release tablet, chewable tablet, and immediate release tablet are approved for ADHD and narcolepsy.
- The efficacy of Adhansia XR for the treatment of ADHD in adults was evaluated in two double-blind studies. Study 1 was a randomized, placebo-controlled study in 375 patients. Study 2 was a randomized, placebo-controlled, cross-over, adult workplace environment study in 90 patients.
    - In study 1, Adhansia XR demonstrated a statistically significant improvement for 45 mg and 100 mg vs. placebo on change of ADHD-Rating Scale (RS) total score from baseline to week 5.
    - In study 2, Adhansia XR demonstrated a statistically significant improvement vs. placebo on the Permanent Measure of Productivity Total (PERMP-T) score, averaged across all timepoints.
- The efficacy of Adhansia XR was also evaluated in a randomized, double-blind, placebo-controlled study (study 3) involving 354 pediatric patients (12 to 17 years) and an analog classroom study (study 4) conducted in 147 pediatric patients 6 to 12 years of age.
    - In study 3, Adhansia XR demonstrated a statistically significant improvement in the ADHS-RS total score vs. placebo at week 5 for the 45 and 70 mg dose groups.
    - In study 4, Adhansia XR demonstrated a statistically significant improvement vs. placebo on the Swanson, Kotkin, Agler, M-Flynn, and Pelham (SKAMP) rating scale (13-item teacher-rated scale that assesses manifestations of ADHD in a classroom setting).
- Adhansia XR carries a boxed warning for abuse and dependence.
- Adhansia XR is contraindicated in patients with hypersensitivity to methylphenidate products or other components in Adhansia XR and concomitant use of monoamine oxidase inhibitors (MAOI) or within 14 days of the last MAOI dose.
- Other warnings and precautions of Adhansia XR include serious cardiovascular reactions, blood pressure and heart rate increases, psychiatric adverse reactions, priapism, peripheral vasculopathy (including Raynaud's phenomenon), long-term suppression of growth, and allergic reactions (contains FD&C Yellow No. 5).
- The most common adverse reactions (≥ 5% and at a rate at least twice placebo) with Adhansia XR use in adults were insomnia, dry mouth, and decreased appetite.
- The most common adverse reactions (≥ 5% and at a rate at least twice placebo) with Adhansia XR use in pediatric patients were decreased appetite, insomnia, and decreased weight.

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- The recommended starting dose of Adhansia XR for patients 6 years or older is 25 mg orally once daily in the morning. The dosage can be titrated in increments of 10 to 15 mg at intervals of no less than 5 days. Dosages higher than 100 mg daily in adults and 85 mg daily in pediatric patients have not been evaluated in clinical trials and are not recommended.

    — Adhansia XR should not be substituted for other methylphenidate products on a milligram-per-milligram basis because of different methylphenidate base compositions and differing pharmacokinetic profiles.

- Purdue Pharma's launch plans for Adhansia XR are pending. Adhansia XR will be available as 25 mg, 35 mg, 45 mg, 55 mg, 70 mg and 85 mg extended-release capsules.