Evekeo ODT™ (amphetamine sulfate) – New drug approval

- On January 30, 2019, the FDA approved Arbor Pharmaceuticals' Evekeo ODT (amphetamine sulfate) orally disintegrating tablets, for the treatment of attention deficit hyperactivity disorder (ADHD) in pediatric patients 6 to 17 years of age.
    - Amphetamine is a Schedule II controlled substance.
- Evekeo is also available generically as immediate-release tablets. In addition to ADHD, this formulation is also indicated for narcolepsy and exogenous obesity.
- The safety and effectiveness of Evekeo ODT for the treatment of ADHD has been established based on an adequate and well-controlled study of immediate-release amphetamine sulfate (Evekeo).
- Evekeo ODT carries a boxed warning for abuse and dependence.
- Evekeo ODT is contraindicated in patients with hypersensitivity to amphetamine products or other ingredients in Evekeo ODT and concomitant use of monoamine oxidase inhibitors (MAOI) or within 14 days of the last MAOI dose.
- Other warnings and precautions of Evekeo ODT include serious cardiovascular reactions, blood pressure and heart rate increases, psychiatric adverse reactions, long-term suppression of growth, seizures, peripheral vasculopathy (including Raynaud's phenomenon), and serotonin syndrome.
- The most common adverse reactions (≥ 4% and at a rate at least twice placebo) with Evekeo ODT use in pediatric patients (6 to 17 years of age) were decreased appetite and insomnia.
- The recommended starting dose of Evekeo ODT is 5 mg once or twice daily. If necessary, an additional dose can be administered after 4 to 6 hours. The dosage can be titrated in increments of 5 mg at weekly intervals until optimal response is obtained. Only in rare cases will it be necessary to exceed a total of 40 mg daily.
    - Prior to treating patients with Evekeo ODT, patients should be assessed for the presence of cardiac disease (ie, perform a careful history, family history of sudden death or ventricular arrhythmia, and physical exam).
    - Patient's risk of abuse should be assessed prior to prescribing and signs of abuse and dependence should be monitored for while on therapy.
    - Switching from Evekeo to Evekeo ODT can be done on a milligram-per-milligram basis.
    - When switching from other amphetamine products, treatment should be discontinued and Evekeo ODT should be titrated as described in the prescribing information. Evekeo ODT should not be substituted for other amphetamine products on a milligram-per-milligram basis because of different amphetamine salt compositions and differing pharmacokinetic profiles.
- Arbor Pharmaceuticals' launch plans for Evekeo ODT are pending. Evekeo ODT will be available as 5 mg, 10 mg, 15 mg, and 20 mg orally disintegrating tablets.