Vyvanse® (lisdexamfetamine dimesylate) – New Formulation Approval

- On January 28, 2017, the FDA approved Shire's Vyvanse (lisdexamfetamine dimesylate) chewable tablets, for the treatment of attention deficit hyperactivity disorder (ADHD) in children 6 years and older and moderate to severe binge eating disorder (BED) in adults.
    - Vyvanse is not indicated or recommended for weight loss. Use of other sympathomimetic drugs for weight loss has been associated with serious cardiovascular (CV) adverse events.
    - The safety and effectiveness of Vyvanse for the treatment of obesity have not been established.
    - Vyvanse is a Schedule II controlled substance.
- Previously, Vyvanse was available as oral capsules. The capsules share the same indications as the chewable tablets.
- Based on pharmacokinetic studies, exposure to lisdexamfetamine and dextroamphetamine was similar between a single dose of Vyvanse 60 mg capsule and a single dose of 60 mg chewable tablet.
- Vyvanse carries a boxed warning for abuse and dependence.
- Vyvanse is contraindicated 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 for Vyvanse include serious CV reactions, blood pressure and heart rate increases, psychiatric adverse reactions, suppression of growth, peripheral vasculopathy, including Raynaud's phenomenon, and serotonin syndrome.
- The most common adverse reactions (≥ 5% and twice that of placebo) with Vyvanse use in children, adolescents, and/or adults with ADHD 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 twice that of placebo) with Vyvanse use in adults with BED were dry mouth, insomnia, decreased appetite, increased heart rate, constipation, feeling jittery, and anxiety.
- For both the Vyvanse chewable tablet and capsule formulations, the recommended starting dose is 30 mg orally once daily.
    - For ADHD, dosage may be adjusted in increments of 10 mg or 20 mg at approximately weekly intervals to achieve the recommended target dose of 30 - 70 mg/day.
    - For BED, dosage may be titrated in increments of 20 mg at approximately weekly intervals to achieve the recommended target dose of 50 - 70 mg/day.
    - For ADHD and BED, the maximum dose is 70 mg/day.
    - Vyvanse capsules can be substituted with Vyvanse chewable tablets on a unit per unit/mg per mg basis.

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- Shire's plans to launch Vyvanse chewable tablets by the end of March 2017. Vyvanse chewable tablets will be available in the following strengths: 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, and 60 mg.