

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 ($\geq 5\%$ 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 ($\geq 5\%$ 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.

- 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.



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