

## Relexxii<sup>®</sup> (methylphenidate hydrochloride extended-release) – New drug approval

- On June 23, 2022, the [FDA approved](#) Vertical Pharmaceuticals' [Relexxii \(methylphenidate hydrochloride extended-release\)](#), for the treatment of attention deficit hyperactivity disorder (ADHD) in adults (up to the age of 65 years) and pediatric patients 6 years of age and older.
  - Relexxii is a Schedule II controlled substance.
- The efficacy of Relexxii is based upon adequate and well-controlled studies of another formulation of methylphenidate hydrochloride extended-release tablets.
- Relexxii carries a boxed warning for abuse and dependence.
- Relexxii is contraindicated in patients:
  - With a known hypersensitivity to methylphenidate or other components of Relexxii.
  - Receiving concomitant treatment with monoamine oxidase inhibitors (MAOIs), and also within 14 days following discontinuation of treatment with a MAOI, because of the risk of hypertensive crisis.
- Additional warnings and precautions for Relexxii 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 potential for gastrointestinal obstruction.
- The most common adverse reactions (> 5%) with Relexxii use in pediatric patients 6 to 17 years was upper abdominal pain. In adult patients, the most common adverse reactions (> 5%) were decreased appetite, headache, dry mouth, nausea, insomnia, anxiety, dizziness, decreased weight, irritability, and hyperhidrosis.
- Relexxii is administered orally once daily in the morning with the starting dose and dosage range depending on age and whether the patient is currently taking methylphenidate or other stimulants. Refer to the Relexxii drug label for complete dosing information.
- Vertical Pharmaceuticals' launch plans for Relexxii are pending. Relexxii will be available as 18 mg, 27 mg, 36 mg, 45 mg, 54 mg, 63 mg, and 72 mg extended-release tablets.