

## Azstarys™ (serdexmethylphenidate/dexmethylphenidate) – New drug approval

- On March 2, 2021, [KemPharm announced](#) the [FDA approval](#) of [Azstarys \(serdexmethylphenidate/dexmethylphenidate\)](#), for the treatment of attention deficit hyperactivity disorder (ADHD) in patients 6 years of age and older.
- Azstarys consists of serdexmethylphenidate, KemPharm's prodrug of d-methylphenidate (d-MPH), co-formulated with immediate-release d-MPH.
- The efficacy of Azstarys was established in a randomized, double-blind, placebo-controlled, analog classroom study in 150 pediatric patients 6 to 12 years of age. The primary endpoint was the mean change from baseline (pre-dose at randomization visit) of the Swanson, Kotkin, Agler, M-Flynn, and Pelham (SKAMP)-Combined scores averaged across the test day (not including baseline score), with assessments conducted at 0.5, 1, 2, 4, 8, 10, 12, and 13 hours post-dose.
  - The mean change from baseline in the SKAMP-Combined scores, averaged across the test day, was statistically significantly lower (indicating improvement) with Azstarys vs. placebo. The placebo-subtracted difference was -5.4 (95% CI: -7.1, -3.7).
- The efficacy of Azstarys in adults and pediatric patients 13 to 17 years of age was established by pharmacokinetic bridging between Azstarys and [dexmethylphenidate](#) extended-release capsules.
- Azstarys carries a boxed warning for abuse and dependence.
- Azstarys is contraindicated in patients:
  - With known hypersensitivity to serdexmethylphenidate, methylphenidate, or other components of Azstarys. Bronchospasm, rash, and pruritus have been reported in patients who received Azstarys. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with other methylphenidate products.
  - Receiving concomitant treatment with monoamine oxidase inhibitors (MAOIs), or within 14 days following discontinuation of treatment with an MAOI, because of the risk of hypertensive crisis.
- Additional warnings and precautions for Azstarys include serious cardiovascular reactions; blood pressure and heart rate increases; psychiatric adverse reactions; priapism; peripheral vasculopathy, including Raynaud's phenomenon; and long-term suppression of growth.
- Based on accumulated data from other methylphenidate products, the most common (> 5% and twice the rate of placebo) adverse reactions with Azstarys use are decreased appetite, insomnia, nausea, vomiting, dyspepsia, abdominal pain, decreased weight, anxiety, dizziness, irritability, affect lability, tachycardia, and increased blood pressure.
- The recommended starting dosage of Azstarys is 39.2 mg serdexmethylphenidate/7.8 mg dexmethylphenidate once daily in the morning.
  - In pediatric patients 6 to 12 years of age, the dosage may be increased after one week to a dosage of 52.3 mg serdexmethylphenidate/10.4 mg dexmethylphenidate per day or decreased after one week to a dosage of 26.1 mg serdexmethylphenidate/5.2 mg dexmethylphenidate per day, depending on response and tolerability.

- In adults and pediatric patients 13 to 17 years of age, the dosage should be increased after one week to a dosage of 52.3 mg serdexmethylphenidate/10.4 mg dexamethylphenidate per day.
- The maximum recommended dosage is 52.3 mg serdexmethylphenidate/10.4 mg dexamethylphenidate once daily.
- If switching from other methylphenidate products, discontinue that treatment, and titrate with Azstarys using the titration schedule described above. Azstarys should not be substituted for other methylphenidate products on a milligram-per-milligram basis because these products have different pharmacokinetic profiles from Azstarys and may have different methylphenidate base composition.
- Azstarys is expected to launch as early as the second half of 2021. Azstarys will be available as a 26.1 mg/5.2 mg, 39.2 mg/7.8 mg, 52.3 mg/10.4 mg capsules (serdexmethylphenidate/dexamethylphenidate).



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