

Azstarys

(serdexmethylphenidate and dexamethylphenidate)

[Full Prescribing Information](#)

[DailyMed Drug Information](#)

Forms/Strengths

- **Capsules:** 26.1 mg/5.2 mg, 39.2 mg/7.8 mg, 52.3 mg/10.4 mg

Dosing

- **Age:** ≥ 6 y/o
- **Onset:** ~ 30 min
- **Duration:** 12-14 hours
- **Release Profile:** 30% IR, 70% ER
- **Considerations:** Administer once daily in the morning, with or without food; capsules can be taken whole or opened and sprinkled onto applesauce or mixed with water.
- **Initial Dose:** 39.2/7.8 mg
- **Titration:** Increase to 52.3/10.4 mg or decrease to 26.1/5.2 mg after one week
- **Max Dose:** 52.3/10.4 mg daily

Quick Facts

- Prodrug
- Extended-release formulation combining immediate-release dexamethylphenidate with a delayed-release prodrug (serdexmethylphenidate) for rapid and sustained effect
- Increases synaptic dopamine and norepinephrine by inhibiting reuptake
- Enhances focus, attention, and impulse control
- Side effects: decreased appetite, insomnia, elevated blood pressure

Indications

- **ADHD** (ICD-10: F90.0)
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Off-Label Uses

- **N/A**
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How to Take

- Take **once daily in the morning** to reduce the risk of insomnia.
 - Can be taken **with or without food**.
 - Swallow the **capsule whole**; do not crush or chew.
 - If needed, the **capsule can be opened, and contents sprinkled on applesauce or water**—consume immediately without chewing.
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Side Effects

- **Common:**
 - Decreased appetite, weight loss
 - Insomnia
 - Headache
 - Nausea, stomach pain
 - Increased heart rate or blood pressure
 - **Serious:**
 - Cardiovascular events: Sudden death in patients with pre-existing structural cardiac abnormalities or arrhythmias.
 - Psychiatric symptoms: New or worsening anxiety, psychosis, or manic symptoms.
 - Peripheral vasculopathy, including Raynaud's phenomenon.
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Monitoring / Labs

- **Cardiovascular:** Baseline and routine monitoring of heart rate and blood pressure.
- **Growth in Pediatrics:** Regular monitoring of height and weight to detect growth suppression.
- **Psychiatric Symptoms:** Observe for mood changes, anxiety, or psychosis.

- **Abuse Potential:** Monitor for misuse or diversion.
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Education

- **When to Call the Doctor:**
 - Severe **mood changes, aggression, or suicidal thoughts**.
 - Chest pain, rapid heartbeat, shortness of breath (**cardiovascular concerns**).
 - Uncontrolled movements, tics, or worsening anxiety.
 - Numbness, coldness, or color changes in fingers or toes (**circulatory issues**).
 - Unexplained weight loss or **delayed growth in pediatric patients**.
 - **Safety Tips:**
 - **Monitor blood pressure and heart rate**, especially in patients with cardiovascular risk.
 - Use caution in patients with **anxiety, bipolar disorder, or psychosis**, as symptoms may worsen.
 - Avoid **caffeine and other stimulants**, which may amplify side effects.
 - Ensure **adequate hydration and nutrition**, as appetite suppression is common.
 - **Tapering may be required** if discontinuing after long-term use.
 - **Parent Tips for Pediatric Patients:**
 - **Encourage a nutrient-dense diet** to counteract appetite suppression.
 - Administer in the **morning before school** for optimal effect.
 - Monitor **school performance and behavioral changes**.
 - Observe for **sleep disturbances**; adjust timing if necessary.
 - Communicate regularly with **teachers and caregivers** about medication effects.
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Additional Information

- **Contraindications:**
 - **Hypersensitivity** to serdexmethylphenidate, dexamethylphenidate, or formulation components.
 - **Use within 14 days of MAOI therapy** (risk of hypertensive crisis).
 - Symptomatic **cardiovascular disease, moderate-to-severe hypertension, hyperthyroidism, glaucoma**.
 - **History of substance use disorder**, unless benefits outweigh risks.
- **Pregnancy:**
 - **Category C**; use only if benefits outweigh risks.
 - May cause **neonatal withdrawal symptoms** or **low birth weight**.
- **Lactation:**
 - **Excreted in breast milk; not recommended** due to potential infant exposure.
- **Drug Interactions:**
 - **Serotonergic drugs** (e.g., SSRIs, SNRIs, MAOIs) increase **serotonin syndrome risk**.

- **Acidifying agents** (e.g., ascorbic acid) may reduce drug absorption.
 - **Alkalinizing agents** (e.g., sodium bicarbonate) may increase dexamethylphenidate levels.
 - May potentiate **hypertensive effects** of certain medications (e.g., decongestants, beta-agonists).
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Revision #17

Created 21 December 2024 13:48:03 by Josh LeJeune NP

Updated 13 February 2025 14:21:41 by Josh LeJeune NP