Azstarys

(serdexmethylphenidate and dexmethylphenidate)

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 formulation**: 30% immediate-release dexmethylphenidate + 70% delayed-release serdexmethylphenidate (converted to dexmethylphenidate in lower GI tract) for rapid onset and sustained 13-hour effect
- Blocks reuptake of **dopamine** and **norepinephrine** into presynaptic neurons, increasing synaptic concentrations
- FDA-approved for **ADHD** in patients ≥6 years; no generic available
- **CII controlled substance** with high abuse potential; monitor for misuse

- Common side effects include **appetite suppression**, **insomnia**, and **increased BP/HR**
- Low incidence of next-day rebound vs. other stimulants due to extended PK profile

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Indications

- **ADHD** (ICD-10: F90.0)

Off-Label Uses

- **N/A**

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.

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.

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.

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.

Additional Information

- **Contraindications:**
  - **Hypersensitivity** to serdexmethylphenidate, dexmethylphenidate, 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 dexmethylphenidate levels.
  - May potentiate **hypertensive effects** of certain medications (e.g., decongestants, beta-agonists).

References

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3. UpToDate: Methylphenidate (dexmethylphenidate), 2025, https://www.uptodate.com/contents/methylphenidate-including-dexmethylphenidate-drug-information
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