

# **Azstarys (Serdexmethylphenidate/ Dexmethylphenidate) — Patient Information Handout**

What is Azstarys?

Azstarys is a prescription medication used to treat Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years of age and older. It contains two active ingredients — serdexmethylphenidate (a prodrug) and dexmethylphenidate — which work together to provide both rapid and long-lasting symptom control throughout the day. Azstarys is a federally controlled substance (Schedule II) because it contains ingredients that can be abused or lead to dependence.

---

How to Take Azstarys

- Take one capsule by mouth once daily in the morning.
  - Azstarys can be taken with or without food.
  - Swallow the capsule whole, OR open the capsule and sprinkle the contents onto applesauce or mix into water. If sprinkled, consume the entire mixture right away — do not store it for later.
  - Do not crush or chew the capsule contents.
  - Your doctor will determine the right dose for you. The usual adult starting dose is 39.2 mg/7.8 mg, which may be increased to 52.3 mg/10.4 mg after one week.
  - Do not change your dose without talking to your doctor.
  - Do not substitute Azstarys for other methylphenidate products on a milligram-per-milligram basis.
- 

Common Side Effects

The following side effects are commonly reported with methylphenidate-based medications like Azstarys:

- Decreased appetite or weight loss

- Trouble sleeping (insomnia)
- Nausea, vomiting, stomach pain, or upset stomach
- Anxiety or irritability
- Mood swings
- Dizziness
- Increased heart rate or blood pressure
- Dry mouth

Many of these side effects may improve over time. Talk to your doctor if any side effect is bothersome or does not go away.

---

### When to Call Your Doctor or Seek Emergency Help

Contact your doctor right away or go to the nearest emergency room if you experience any of the following:

- Chest pain, shortness of breath, or fainting — these could be signs of a heart problem.
  - New or worsening mental health symptoms, including hearing or seeing things that are not there (hallucinations), feeling unusually suspicious, or feeling extremely "high" or manic.
  - A painful erection lasting more than 4 hours (priapism) — this is a medical emergency.
  - Numbness, coolness, pain, color changes, or sensitivity to temperature in your fingers or toes (signs of circulation problems, including Raynaud's phenomenon).
  - Signs of a severe allergic reaction: rash, hives, swelling of the face/lips/tongue/throat, or difficulty breathing.
  - New or worsening tics (sudden, repeated movements or sounds).
-

## Important Safety Information

- **Heart conditions:** Tell your doctor if you have any heart problems, a family history of sudden death, or irregular heartbeat. Azstarys should not be used in patients with serious heart conditions.
  - **Blood pressure and heart rate:** Azstarys can raise your blood pressure and heart rate. Your doctor should check these regularly.
  - **Mental health history:** Let your doctor know if you or your family have a history of depression, bipolar disorder, or psychosis.
  - **Pregnancy and breastfeeding:** Talk to your doctor if you are pregnant, planning to become pregnant, or breastfeeding.
  - **Substance use:** Because Azstarys is a controlled substance, it should be stored securely and never shared with others. Misuse can cause serious side effects, including death.
- 

## Drug Interactions — Tell Your Doctor About All Medications You Take

Certain medications can interact with Azstarys:

- **MAO inhibitors (MAOIs):** Do not take Azstarys if you are taking or have taken an MAOI within the past 14 days. Combining these can cause a dangerous spike in blood pressure (hypertensive crisis).
  - **Blood pressure medications:** Azstarys may reduce the effectiveness of blood pressure drugs. Your doctor may need to adjust your dose.
  - **Risperidone:** Taking Azstarys with risperidone may increase the risk of involuntary muscle movements.
  - **Anesthesia:** If you are having surgery, tell your surgeon and anesthesiologist that you take Azstarys. You should not take it on the day of surgery if halogenated anesthetics will be used.
- 

## Storage and Handling

- Store Azstarys at room temperature, away from light and moisture.
- Keep it in a safe, secure place — preferably locked — to prevent misuse.

- Keep out of reach of children.
  - Dispose of any unused medication properly. Ask your pharmacist about safe disposal options.
- 

### Questions?

If you have questions about Azstarys, talk to your doctor or pharmacist. To report side effects, contact Corium, LLC at 1-855-253-2407 or the FDA at 1-800-FDA-1088.