

AZSTARYS®: For your adult patients with ADHD¹



serdexmethylphenidate
and dexmethylphenidate

26.1/5.2mg • 39.2/7.8mg • 52.3/10.4mg capsules

For
adults

**Redefine how you
control ADHD**

**AZSTARYS is the first and only d-MPH with novel
SDX prodrug and IR activity^{1,2}**

d-MPH, dexmethylphenidate; IR, immediate-release; SDX, serdexmethylphenidate.

INDICATION

AZSTARYS is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.

IMPORTANT SAFETY INFORMATION

WARNING: ABUSE AND DEPENDENCE

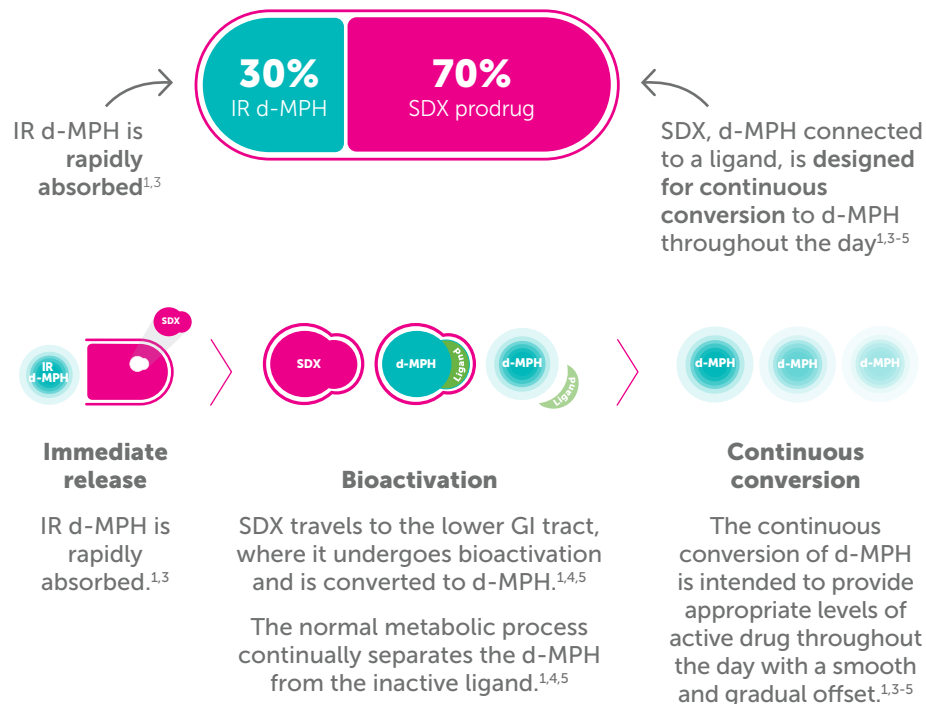
- CNS stimulants, including AZSTARYS, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy

Please see additional Important Safety Information throughout and [click here](#) for Full Prescribing Information, including Boxed WARNING.

Only AZSTARYS combines the SDX prodrug and IR d-MPH^{1,2}

AZSTARYS uses proprietary Ligand Activated Therapy® technology in the novel SDX prodrug that is designed to control levels of d-MPH throughout the day^{3,4}

The unique once-daily capsule contains^{1,2}



GI, gastrointestinal.

The Ligand Activated Therapy, or LAT, platform, is a registered trademark of KemPharm.

IMPORTANT SAFETY INFORMATION (continued)

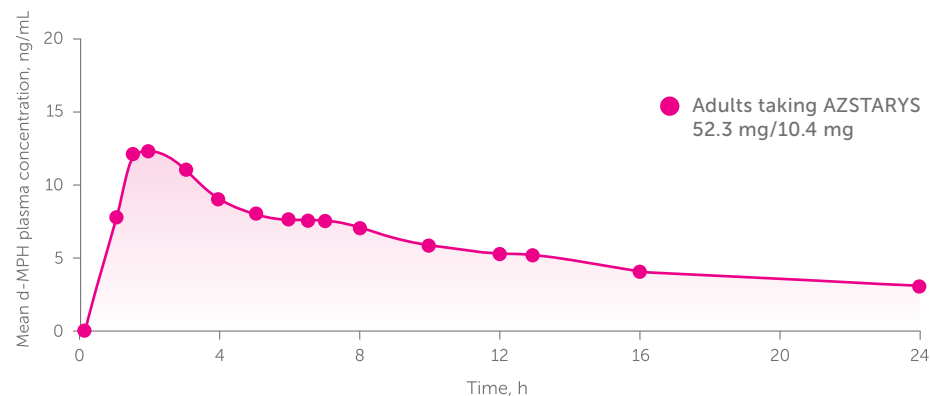
Contraindications

- Known hypersensitivity to serdexmethylphenidate, methylphenidate, or other product components. Bronchospasm, rash, and pruritus have occurred with AZSTARYS. Hypersensitivity reactions such as angioedema and anaphylactic reactions have occurred with other methylphenidate products.

AZSTARYS continuously converts controlled amounts of d-MPH throughout the day¹⁻⁴

The first and only IR d-MPH and novel SDX prodrug enables rapid absorption, followed by a gradual decline in d-MPH exposure¹⁻³

PK study in adults: Mean plasma concentrations of d-MPH measured throughout the day^{1,a}



- d-MPH levels rise rapidly¹
- d-MPH levels peak at 2 hours while SDX is converted to d-MPH^{1,3}
- Continuous conversion extends d-MPH throughout the day^{1,3}
- d-MPH levels gradually decline¹

PK, pharmacokinetic.

^aFollowing a single dose of AZSTARYS in healthy adults under fasted conditions. Mean plasma concentrations continued to gradually decline through 72 hours post dose.¹

IMPORTANT SAFETY INFORMATION (continued)

Contraindications (continued)

- Concomitant treatment with a monoamine oxidase inhibitor (MAOI) or use of an MAOI within the preceding 14 days, because of the risk of hypertensive crisis.

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INADEQUATE SYMPTOM CONTROL



Not actual patient.

Current ER medication does not last long enough to control ADHD symptoms

PATIENT WITH ADHD

Name: **Sean**

Age: **25 years**

Sex: **Male**

Current treatment: **MPH ER stimulant**

TREATMENT HISTORY

- Diagnosed with ADHD at age 10 years
- Initially treated with AMP
- Multiple switched medications to balance coverage and tolerability

ADULT PATIENT CHALLENGES

- Distracted in the morning and runs late for appointments
- Received customer complaints for lack of attention to detail during the late afternoon
- Complained about appetite suppression on prior AMP therapy
- Tolerates current MPH medication well but struggles with a lack of symptom control

AMP, amphetamine; ER, extended-release; MPH, methylphenidate.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions

- Sudden death has been reported in association with CNS stimulant treatment at recommended doses in pediatric patients with structural cardiac abnormalities or other serious heart problems. In adults, sudden death, stroke, and myocardial infarction have been reported at recommended doses. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmias, coronary artery disease, or other serious heart problems.

NEWLY DIAGNOSED



Not actual patient.

Recently diagnosed with inattentive subtype ADHD

PATIENT WITH ADHD

Name: **Sarah**

Age: **42 years**

Sex: **Female**

Current treatment: **None**

FAMILY HISTORY

- 12-year-old son with ADHD taking an AMP ER stimulant for the past 4 years
- History of anxiety

ADULT PATIENT CHALLENGES

- Worries she may lose her job
- Lacks focus at work
- Frequently misses deadlines
- Forgets appointments
- Wants effective control while considering history of anxiety

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- CNS stimulants cause an increase in blood pressure and heart rate. Monitor all patients for hypertension and tachycardia.

Please see additional Important Safety Information throughout and [click here](#) for Full Prescribing Information, including Boxed WARNING.

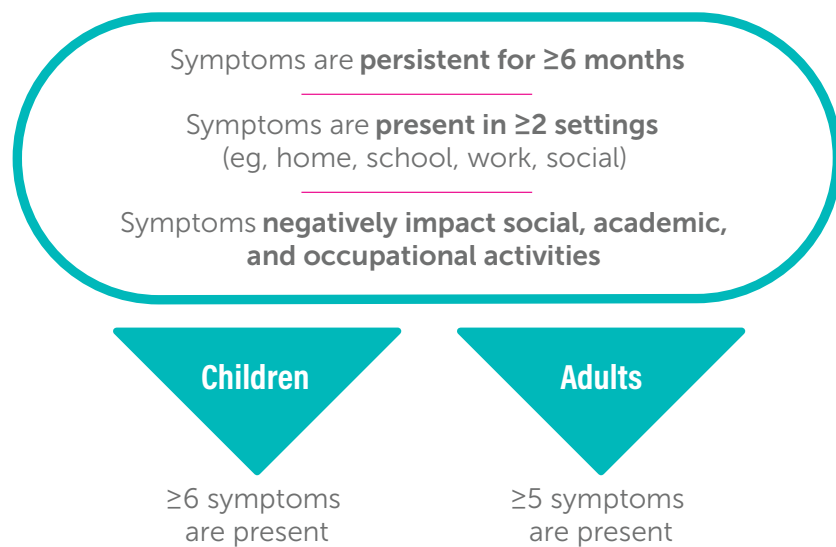


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DSM-5 diagnostic criteria for ADHD in childhood and adulthood differ based on symptomatology⁶

The DSM-5 states that a diagnosis of ADHD can be made when



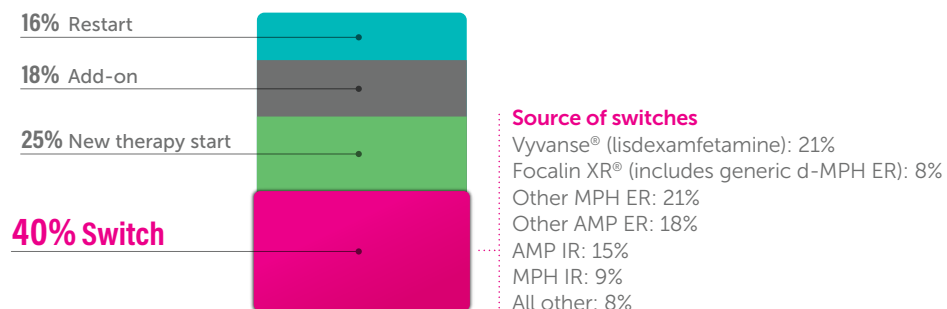
Adapted from the DSM-5.
DSM-5, *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.*

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- **Exacerbation of Pre-existing Psychosis:** May exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder. **Induction of a Manic Episode in Patients with Bipolar Disorder:** May induce a mixed/manic episode in patients with bipolar disorder. Prior to initiating treatment, screen for risk factors for developing a manic episode (e.g., comorbid or history of depressive symptoms, or a family history of suicide, bipolar disorder, or depression). **New Psychotic or Manic Symptoms:** At recommended doses, may cause psychotic or manic symptoms (e.g., hallucinations, delusional thinking, or mania) in patients without a history of psychotic illness or mania. Discontinue if symptoms occur.

40% of adult patients on AZSTARYS switched from another regimen⁷



Adult AZSTARYS patients by most recent previous treatment (N=2033)

Source: IQVIA XPD prescriber dynamics data 7/1/2021 through 4/8/2022.
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IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- Cases of painful and prolonged penile erections and priapism have been reported with methylphenidate products. Immediate medical attention should be sought if signs or symptoms of prolonged penile erections or priapism are observed.

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IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- CNS stimulants, including AZSTARYS, are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; very rare sequelae include digital ulceration and/or soft tissue breakdown. Carefully observe patients during treatment for digital changes. Further evaluation may be required, including referral.
- CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients. Monitor height and weight at appropriate intervals in pediatric patients. Treatment may need to be interrupted in children not growing or gaining weight as expected.

Adverse Reactions

- Based on accumulated data from other methylphenidate products, the most common (>5% and twice the rate of placebo) adverse reactions are appetite decreased, insomnia, nausea, vomiting, dyspepsia, abdominal pain, weight decreased, anxiety, dizziness, irritability, affect lability, tachycardia, and blood pressure increased.

Drug Interactions

- Adjust dosage of antihypertensive drug as needed. Monitor blood pressure.
- Avoid use of AZSTARYS on the day of surgery if halogenated anesthetics will be used.

References: **1.** AZSTARYS. Prescribing information. Corium, Inc; 2021. **2.** Mickle T, Guenther S, Chi G, inventors; KemPharm, Inc, assignee. Methylphenidate-prodrugs, processes of making and using the same. U.S. patent 10,584,113. March 10, 2020. **3.** Childress AC, Komolova M, Sallee FR. An update on the pharmacokinetic considerations in the treatment of ADHD with long-acting methylphenidate and amphetamine formulations. *Expert Opin Drug Metab Toxicol.* 2019;15(11):937-974. doi:10.1080/17425255.2019.1675636 **4.** Patrick KS, Radke JL, Raymond JR, et al. Drug regimen individualization for attention-deficit/hyperactivity disorder: guidance for methylphenidate and dexamethylphenidate formulations. *Pharmacotherapy.* 2019;39(6):677-688. doi:10.1002/phar.2190 **5.** Gudín JA, Nalamachu SR. An overview of prodrug technology and its application for developing abuse-deterrent opioids. *Postgrad Med.* 2016;128(1):97-105. doi:10.1080/00325481.2016.1126186 **6.** American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders.* 5th ed. 2013. **7.** Data on file. Corium, Inc. **8.** Kollins SH, Braeckman R, Guenther S, et al. A randomized, controlled laboratory classroom study of serdexmethylphenidate and d-methylphenidate capsules in children with attention-deficit/hyperactivity disorder. *J Child Adolesc Psychopharmacol.* 2021;31(9):597-609. doi:10.1089/cap.2021.0077

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The **FIRST** and **ONLY** d-MPH with novel SDX prodrug and IR activity^{1,2}

- **Rapid onset** for the early morning routine^{1,8}
- **Sustained control** of symptoms during and after work^{1,8}
- **Smooth and gradual offset** through the evening^{1,8}

\$0 for their first prescription for eligible patients^a

Scan the QR code or visit [AZSTARYS-pro.com](https://www.azstarys-pro.com) to learn more and register for updates



^aRestrictions may apply. See Terms and Conditions at [AZSTARYS.com](https://www.azstarys.com).

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COM-AZS-003239 08/22


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