AZSTARYS™ is the first and only d-MPH with novel SDX prodrug and IR activity for symptom coverage throughout your patient's day[1-3]

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**

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

Please see additional Important Safety Information throughout and click here for Full Prescribing Information, including Boxed WARNING.

azstarys™ (II)

serdexmethylphenidate and dexmethylphenidate

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

Only AZSTARYS combines the novel SDX prodrug and IR d-MPH[1,2]

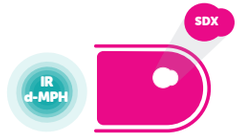
AZSTARYS uses proprietary Ligand Activated Therapy® technology in the novel SDX prodrug that is designed to control levels of d-MPH throughout the day[3,4]

The unique once-daily capsule contains[1,2]

IR d-MPH is **rapidly absorbed**[1,3]

SDX, d-MPH connected to a ligand, is **designed for continuous conversion to** d-MPH throughout the day[1,3-5]

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



Immediate release

IR d-MPH is rapidly absorbed.[1,3]

Bioactivation

SDX travels to the lower GI tract, where it undergoes bioactivation and is converted to d-MPH.[1,4,5]

The normal metabolic process continually separates the d-MPH from the inactive ligand.[1,4,5]

Continuous conversion

The continuous conversion of d-MPH is intended to provide appropriate levels of active drug throughout the day with a gradual offset.[1,3-5]

GI, gastrointestinal.

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.
- 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.

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

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.

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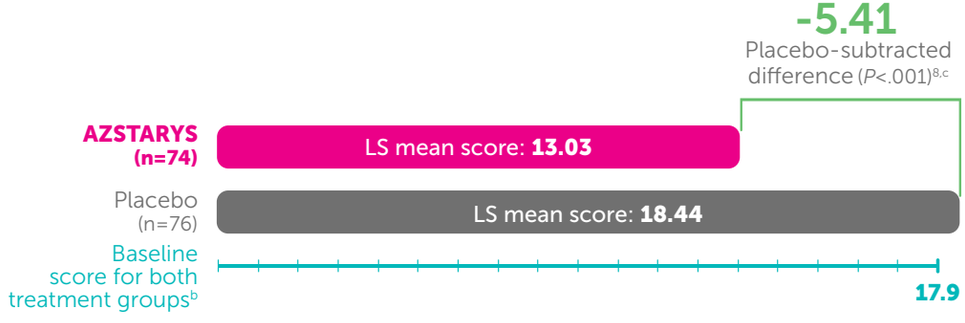
AZSTARYS provides a unique approach to symptom coverage[1,2]

With an IR d-MPH and SDX prodrug, AZSTARYS provides efficacy throughout the day[1]

Improvement in ADHD symptoms was demonstrated in a clinical trial using SKAMP, a 13-item validated assessment of classroom behaviors in children with ADHD,[1] including[6,7,a]

- Attention
- Deportment
- Quality of written work
- Compliance

AZSTARYS significantly lowered SKAMP-C scores averaged over the 13-hour test day[1]



The primary end point was the mean change from baseline of SKAMP-C scores averaged over 13 hours. Assessments were conducted at baseline and 0.5, 1, 2, 4, 8, 10, 12, and 13 hours post dose. The LS mean change from baseline was -4.87 with AZSTARYS and 0.54 with placebo.[1]

LS, least squares; SKAMP, Swanson, Kotkin, Agler, M-Flynn, and Pelham; SKAMP-C, Swanson, Kotkin, Agler, M-Flynn, and Pelham-Combined.

[a]A decrease in SKAMP-C scores indicates symptom improvement.[1]

[b]Baseline score assessed at predose on the practice classroom day/randomization visit after 2 days of active drug washout.[1]

[c]Difference (active drug minus placebo) in LS mean change from baseline.[1]

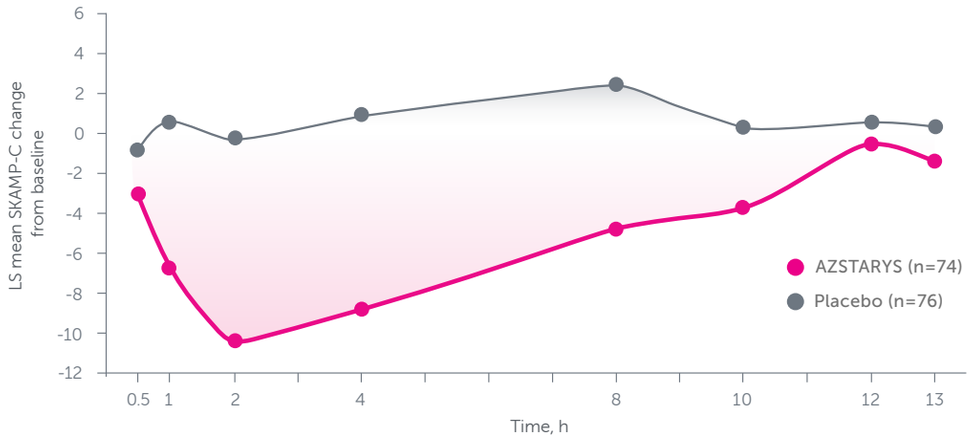
IMPORTANT SAFETY INFORMATION (continued)

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.

AZSTARYS provides both rapid onset and extended duration of efficacy with a once-daily dose[1]

AZSTARYS lowered mean SKAMP-C scores from baseline throughout the day



Rapid onset for the morning routine › **Sustained efficacy throughout school and daily activities** › **Extended duration of effect with a gradual offset**

Study design: A randomized, double-blind, placebo-controlled, parallel-group, analog classroom study of 150 pediatric patients (aged 6-12 years) with ADHD. During the open-label dose-optimization phase (3 weeks), patients received AZSTARYS 39.2 mg/7.8 mg once daily. The dose could be titrated weekly to 26.1 mg/5.2 mg, 39.2 mg/7.8 mg, or 52.3 mg/10.4 mg (maximum dose). After 1 week, raters evaluated patients' attention and behavior in a laboratory classroom setting over 13 hours using the SKAMP-C Rating Scale.[1]

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.

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AZSTARYS provides symptom coverage throughout the day with a once-daily dose[1]

Available in 3 dosage strengths to meet the individual needs of your patients

26.1 mg/ 5.2 mg	39.2 mg/7.8 mg Recommended starting dose once daily	52.3 mg/ 10.4 mg

Graphic is for comparative purposes only. Not actual size.

AZSTARYS capsule design

- The capsule size is the same across the 3 dosage strengths
- Each dosage strength is colored differently to reduce confusion and administration errors

Titration

- Dosage may be titrated after 1 week, if needed
  - For patients aged 6 to 12 years, the dosage may be increased to 52.3 mg/10.4 mg or decreased to 26.1 mg/5.2 mg once daily
  - For adults and pediatric patients aged 13 to 17 years, dosage may be increased to 52.3 mg/10.4 mg once daily
- The maximum daily dose is 52.3 mg/10.4 mg

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- 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.

Convenient once-daily dosing to fit the morning routine[1]

AZSTARYS has 3 flexible administration options

Swallow whole

Small-sized capsules for patients who prefer to swallow them whole

or

Sprinkle into water

The capsule may be opened and its contents sprinkled into 2 oz (50 mL) of water[a]

or

Sprinkle onto applesauce

The capsule may be opened and its contents may be sprinkled over 2 tablespoons of applesauce[a]

AZSTARYS may be taken with or without food

[a]The mixture should be consumed within 10 minutes and cannot be stored for future use.

IMPORTANT SAFETY INFORMATION (continued)

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.

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Safety in patients aged 6 years and older[1]

Clinical trial experience with other MPH products in pediatric patients and adults with ADHD

Commonly reported (≥5% of the MPH group and at least twice the rate of the placebo group) adverse reactions from placebo-controlled trials of MPH products included decreased appetite, decreased weight, nausea, abdominal pain, dyspepsia, vomiting, insomnia, anxiety, affect lability, irritability, dizziness, increased blood pressure, and tachycardia.

Weight and height changes in patients aged 6 to 12 years over 12 months[a]

	Mean increase	Mean z-score[b]
Weight	3.4 kg	-0.20
Height	4.9 cm	-0.21

Mean change in z-scores from baseline to Month 12 for both weight and height indicated a lower-than-expected increase compared with children of the same age and sex, on average. **A z-score change <0.5 SD is considered not clinically significant.**

MPH, methylphenidate.

[a]A long-term, open-label safety study was conducted in pediatric patients aged 6 to 12 years with ADHD. This study was comprised of a 3-week dose-optimization phase for patients not recently treated with AZSTARYS (from the primary short-term study), followed by a 12-month treatment phase for all patients during which 238 received open-label AZSTARYS and had evaluable safety data. A total of 154 patients were treated for 12 months. Because of the open-label, uncontrolled design of this study, the reported adverse reaction rates cannot be assessed in terms of a causal relationship to AZSTARYS treatment.

[b]Z-scores show the SD above or below the mean weight or height normalized for the natural growth of children and adolescents by comparison to age- and sex-matched population standards.

IMPORTANT SAFETY INFORMATION (continued)

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.

CoriumCares offers support for patients prescribed AZSTARYS

The CoriumCares program provides copay assistance, access support, and educational resources for patients.

There are 3 ways to help eligible patients access the support they need

1

Patients can register for copay savings at **AZSTARYS.com**.

Eligible patients may pay as little as $0 for their first prescription. For refills, patients may pay as little as $50 if their insurance covers AZSTARYS or as little as $75 if their insurance does not cover AZSTARYS.[c]

2

Patients or their caregivers can call **1-800-910-8432** for information about CoriumCares support, such as

- Resources for patients starting treatment
- Assistance with prior authorization and other access resources
- Ongoing call center support for questions

3

Give your patients and their caregivers the **Welcome Kit** provided by Corium so they have all the information they need when starting AZSTARYS.

[c]Restrictions and a maximum benefit may apply. See Terms and Conditions at AZSTARYS.com.

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 dexmethylphenidate formulations. *Pharmacotherapy*. 2019;39(6):677-688. doi:10.1002/phar.2190 **5.** Gudin 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.** Wigal SB. Laboratory school protocol mini-review: use of direct observational and objective measures to assess ADHD treatment response across the lifespan. *Front Psychol.* 2019;10:1796. doi:10.3389/fpsyg.2019.01796 **7.** Wigal SB, Wigal TL. The laboratory school protocol: its origin, use, and new applications. *J Atten Disord*. 2006;10(1): 92-111. doi:10.1177/1087054705286049 **8.** Data on file. Corium Inc.

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A consistent day can make all the difference

AZSTARYS is the first and only d-MPH with novel SDX prodrug and IR activity for symptom coverage throughout your patient's day[1-3]

For patients with ADHD aged 6 years and older[1]

- Novel SDX prodrug bioactivated for continuous conversion to d-MPH[1,3-5]
- Rapid onset and extended symptom coverage with a gradual offset[1]
- Convenient once-daily dosing with flexible administration options[1]

CoriumCares™ gives eligible patients access to helpful support and copay savings.

Visit AZSTARYS.com to learn more and register for updates

INDICATION

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