For your patients aged 6 and up with ADHD

AZSTARYS®—a prodrug innovation that redefines how ADHD is controlled[1,2]

FIRST and *ONLY* d-MPH with novel SDX prodrug and IR activity[1,2]

Actor portrayals.

Rapid onset in the early morning[1,3]

Sustained control of symptoms throughout the day[1,3]

Smooth and gradual offset into the evening[1,3]

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, MISUSE, AND ADDICTION

AZSTARYS has a high potential for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Misuse and abuse of CNS stimulants, including AZSTARYS, can result in overdose and death and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.

Before prescribing AZSTARYS, assess each patient's risk for abuse, misuse, and addiction. Educate patients and their families about these risks, proper storage of the drug, and proper disposal of any unused drug. Throughout treatment, reassess each patient's risk and frequently monitor for signs and symptoms of abuse, misuse, and addiction.

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

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For your patients with ADHD,

Which parts of the day are most challenging?

Morning

Distracted and **disorganized** without ADHD symptom control

Midday

Difficulty focusing while waiting for the medication to kick in

Afternoon

Struggles with **uncontrolled ADHD symptoms**

End of day

Restless and **impulsive** during the evening

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 in patients treated 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.

Facts about ADHD

DSM-5 diagnostic criteria for ADHD in childhood and adulthood differ based on symptomatology[4]

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

- Symptoms are **persistent for ≥6 months**
- Symptoms are **present in ≥2 settings** (eg, home, school, work, social)
- Symptoms **negatively impact social, academic, and occupational activities**

Adults
≥5 symptoms are present

or

Children
≥6 symptoms are present

Adapted from *DSM-5*; not a complete list.

ADHD by the numbers

10%
of children are diagnosed with **ADHD**[5]

60%
of patients are estimated to **carry ADHD into adulthood**[6]

41% to 55%
of families with at least 1 child with ADHD also **have at least 1 parent with ADHD**[7,8]

DSM-5, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions

- Sudden death has been reported in patients with structural cardiac abnormalities or other serious cardiac disease who were treated with CNS stimulants at the recommended ADHD dosage. Avoid AZSTARYS use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery disease, or other serious cardiac disease.
- CNS stimulants cause an increase in blood pressure and heart rate. Monitor all AZSTARYS-treated patients for hypertension and tachycardia.

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Consider **AZSTARYS** for your patients with ADHD

Current treatment: **MPH ER**	Struggling with uncontrolled ADHD symptoms despite current treatment

Patient with ADHD
Name: **Tyler**
Age: **10 years**
Sex: **Male**

Treatment history
- Diagnosed with ADHD at age 8 years
- Initially treated with IR MPH

Patient challenges
- Often distracted and disorganized in the morning
- After-school activities and homework affected by return of symptoms in the afternoon
- Restless and disruptive during family time in the evening

Is now the time to consider switching to AZSTARYS?

Not actual patient.

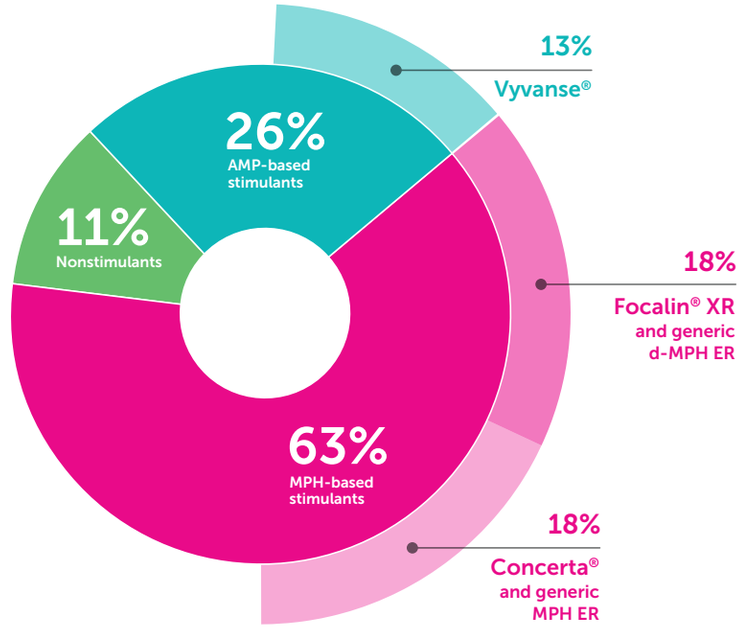
ER, extended-release; MPH, methylphenidate.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- *Exacerbation of Pre-existing Psychosis*: CNS stimulants 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*: CNS stimulants may induce a mixed mood/manic episode in patients with bipolar disorder. Prior to initiating AZSTARYS 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*: CNS stimulants at the recommended dosage may cause psychotic or manic symptoms (e.g., hallucinations, delusional thinking, or mania) in patients without a history of psychotic illness or mania. Consider discontinuing AZSTARYS if symptoms occur.
- Cases of painful and prolonged penile erections and priapism have been reported with methylphenidate use, in both adult and pediatric male patients. AZSTARYS-treated patients who develop abnormally sustained or frequent and painful erections should seek immediate medical attention.
- CNS stimulants, including AZSTARYS, are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; however, sequelae have included digital ulceration and/or soft tissue breakdown. Carefully observe patients during AZSTARYS treatment for digital changes. Further clinical evaluation may be appropriate for patients who develop signs or symptoms of peripheral vasculopathy.

86% of pediatric and adolescent patients on **AZSTARYS** switched from another regimen[9,a]



63% of patients switch from other MPH-based stimulants

AMP, amphetamine.

[a]**Source: IQVIA ADHD LAAD data from January 2022 through December 2022, with 17,349 prescriptions dispensed for pediatric and adolescent patients (aged <18 years).**

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients. Closely monitor height and weight at appropriate intervals in AZSTARYS-treated pediatric patients. Treatment may need to be interrupted in pediatric patients not growing or gaining weight as expected.
- Angle closure glaucoma associated with methylphenidate treatment has been reported. AZSTARYS-treated patients considered at risk for acute angle closure glaucoma should be evaluated by an ophthalmologist.

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Consider **AZSTARYS** for your patients with ADHD

Current treatment: **AMP ER**	Continues to experience ADHD symptoms

Not actual patient.

Patient with ADHD

Name: **Kevin**
Age: **25 years**
Sex: **Male**

Treatment history

- Diagnosed with ADHD at age 10 years
- History of medication breaks and titration with AMP-based medications

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
- Prefers a prodrug and thinks it is time to try something different

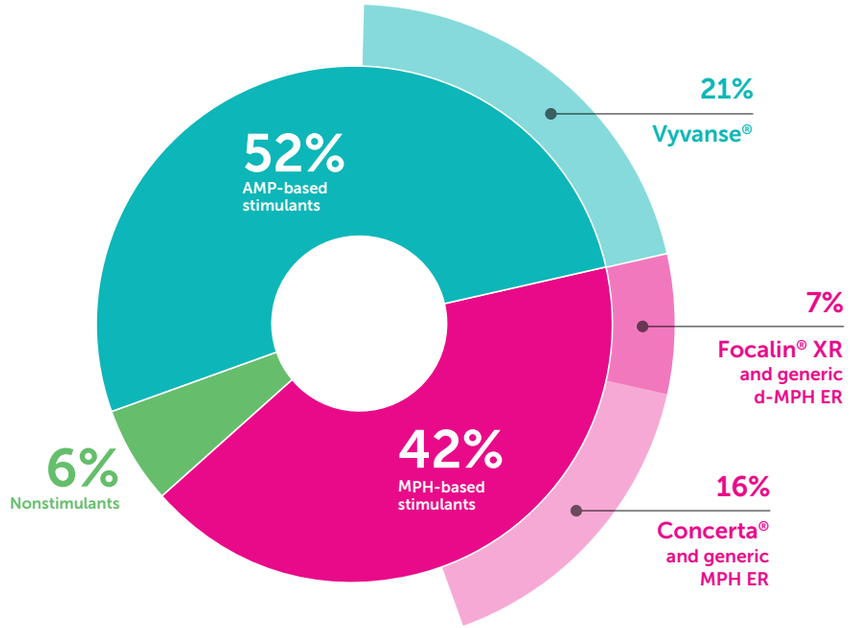
Is now the time to consider switching to AZSTARYS?

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- Elevation of intraocular pressure (IOP) associated with methylphenidate treatment has been reported. Use of AZSTARYS with patients who have open-angle glaucoma or abnormally increased IOP should only be considered if the benefit of treatment outweighs the risk. Closely monitor AZSTARYS-treated patients with a history of abnormally increased IOP or open angle glaucoma.
- CNS stimulants, including methylphenidate, have been associated with the onset or exacerbation of motor and verbal tics. Worsening of Tourette's syndrome has also been reported. Before initiating AZSTARYS, assess family history and clinically evaluate patients for tics or Tourette's syndrome. Regularly monitor AZSTARYS-treated patients for the emergence or worsening of tics or Tourette's syndrome, and discontinue treatment if clinically appropriate.

80% of adult patients on **AZSTARYS** switched from another regimen[9,a]



52%
of patients switch from AMP-based stimulants

[a]**Source: IQVIA ADHD LAAD data from January 2022 through December 2022, with 11,756 prescriptions dispensed for adult patients.**

IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions

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

Drug Interactions

- Adjust dosage of antihypertensive drug as needed. Monitor blood pressure.

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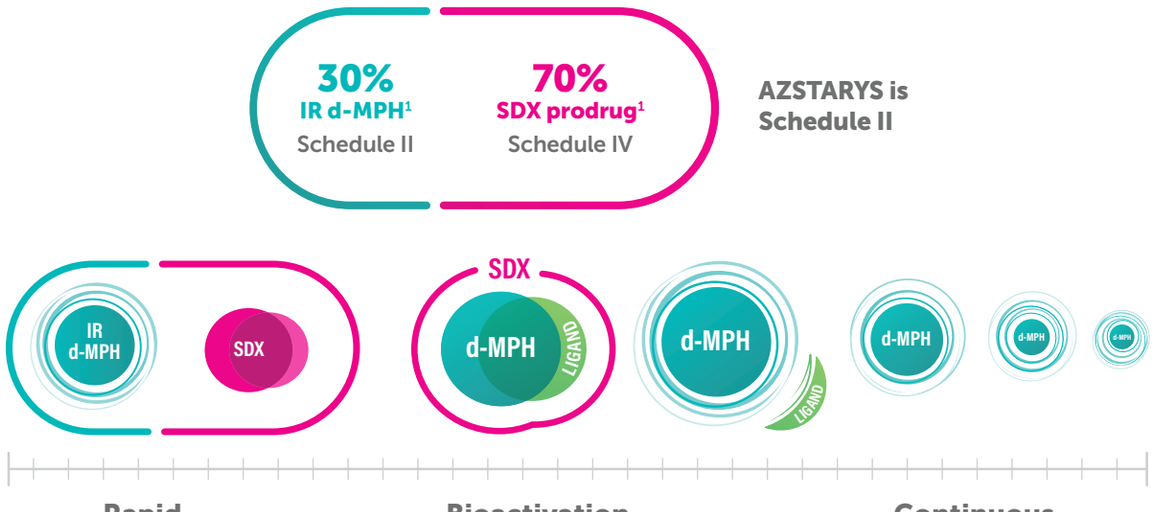
AZSTARYS is designed to provide immediate and extended d-MPH activity with a smooth and gradual offset[1,3,10]



GI, gastrointestinal.

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

SDX is a complex of d-MPH and a serine amino acid ligand. In the lower GI tract, the serine ligand is cleaved off, uniformly producing active d-MPH. The serine moiety is inert and has no biologic activity.[2,10-12]

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

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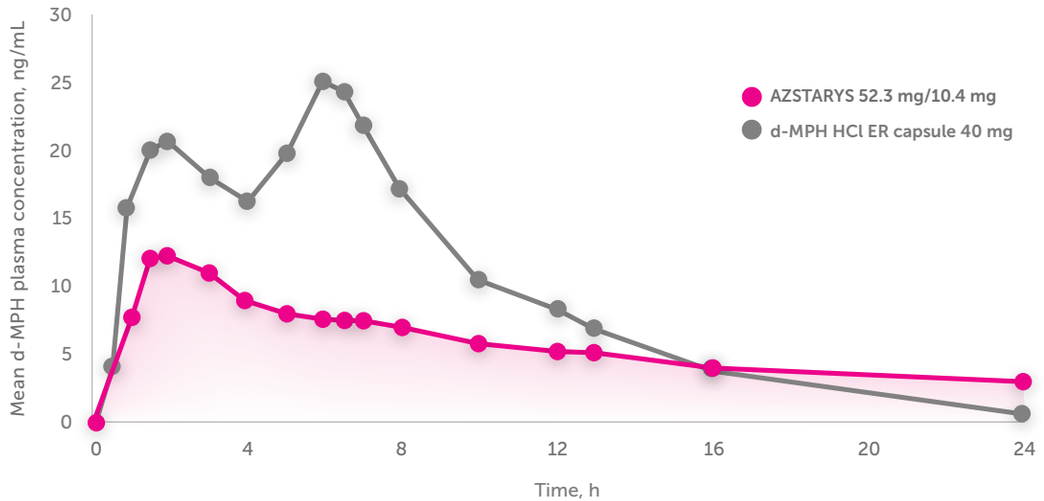
Unlike the dual peaks and troughs associated with d-MPH HCl ER, **AZSTARYS features a rapid rise, followed by a smooth and gradual decline in d-MPH**[1]

PK study in healthy adults: mean plasma concentrations of d-MPH measured throughout the day[1,a]



Results are from a PK study of AZSTARYS in healthy adults under fasted conditions.[1,a] The clinical relevance of these data has not been established.

HCl, hydrochloride; PK, pharmacokinetics.

[a]Plasma concentrations were measured following a single dose of AZSTARYS or d-MPH HCl ER capsule. Mean plasma concentrations continued to gradually decline through 72 hours post dose.[1]

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 in patients treated 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 patients with structural cardiac abnormalities or other serious cardiac disease who were treated with CNS stimulants at the recommended ADHD dosage. Avoid AZSTARYS use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery disease, or other serious cardiac disease.

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AZSTARYS demonstrated efficacy across clinical assessments in patients aged 6 to 12 years[1,3]

SKAMP-C[1,a]

Primary end point and key secondary end points

Rapid and sustained improvement in classroom behaviors throughout the day

PERMP math tests[3,b]

Secondary end point

Rapid **30-minute** onset and extended **13-hour** duration

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). For the treatment phase, after a 2-day washout period, patients were randomly assigned to either continue receiving the individually optimized dose of AZSTARYS or placebo for 7 days. Efficacy was evaluated in a laboratory classroom setting over 13 hours using the SKAMP and PERMP rating scales. Assessments were conducted at baseline and 0.5, 1, 2, 4, 8, 10, 12, and 13 hours post dose.[1,3]

PERMP, Permanent Product Measure of Performance; SKAMP, Swanson, Kotkin, Agler, M-Flynn, and Pelham; SKAMP-C, Swanson, Kotkin, Agler, M-Flynn, and Pelham-Combined.

[a]SKAMP is a 13-item assessment of classroom behaviors in children with ADHD, including attention, deportment, quality of work, and compliance.[3]

[b]PERMP is a 400-problem, validated, skill-adjusted mathematics test that objectively measures a patient's ability to complete as many problems as possible in 10 minutes.[3,9]

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

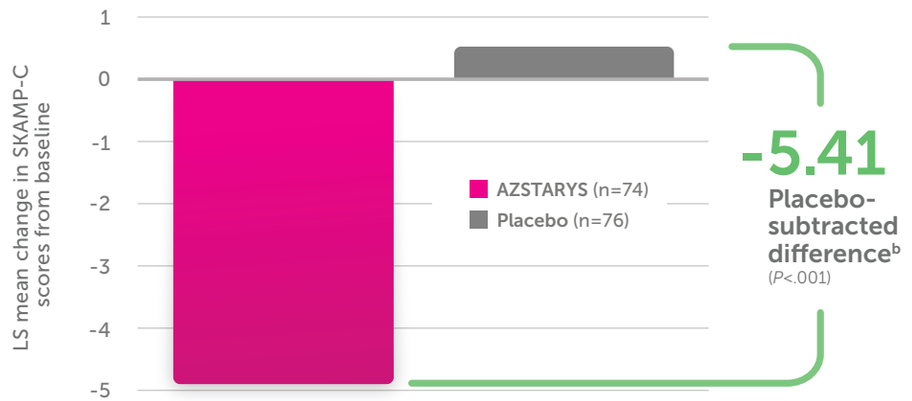
- CNS stimulants cause an increase in blood pressure and heart rate. Monitor all AZSTARYS-treated patients for hypertension and tachycardia.
- *Exacerbation of Pre-existing Psychosis*: CNS stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder. *Induction of a Manic Episode in Patients with Bipolar Disorder*: CNS stimulants may induce a mixed mood/manic episode in patients with bipolar disorder. Prior to initiating AZSTARYS 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*: CNS stimulants at the recommended dosage may cause psychotic or manic symptoms (e.g., hallucinations, delusional thinking, or mania) in patients without a history of psychotic illness or mania. Consider discontinuing AZSTARYS if symptoms occur.
- Cases of painful and prolonged penile erections and priapism have been reported with methylphenidate use, in both adult and pediatric male patients. AZSTARYS-treated patients who develop abnormally sustained or frequent and painful erections should seek immediate medical attention.

Improves ADHD classroom behaviors throughout the day[1]

AZSTARYS significantly lowered SKAMP-C scores assessing[1,3]

Attention | Deportment | Quality of work | Compliance

Primary end point in patients aged 6 to 12 years:
LS mean change from baseline in SKAMP-C scores averaged over 13 hours[1,3,a]



LS, least squares.

[a]Predose Visit 5 as baseline. Baseline score was 17.9 for both groups.[1]

[b]Difference (active drug minus placebo) in LS mean change from baseline.[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; however, sequelae have included digital ulceration and/or soft tissue breakdown. Carefully observe patients during AZSTARYS treatment for digital changes. Further clinical evaluation may be appropriate for patients who develop signs or symptoms of peripheral vasculopathy.
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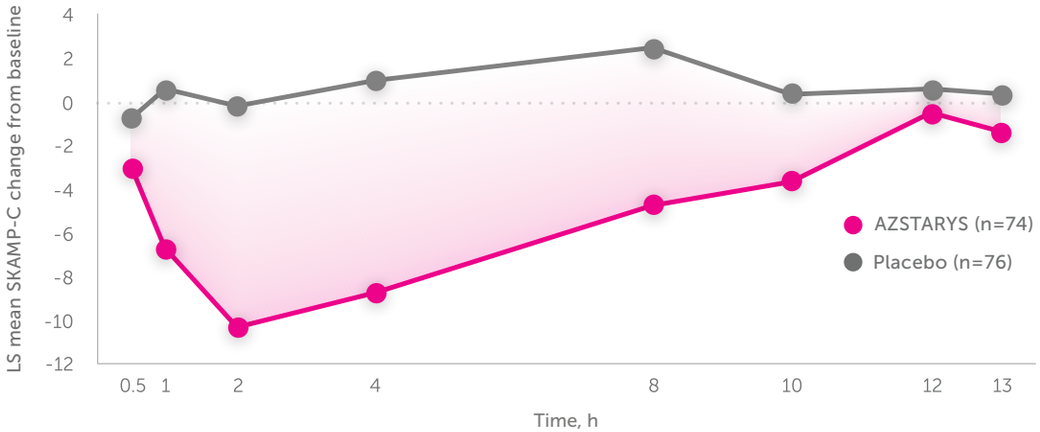
Rapid onset and extended duration of efficacy throughout the day[1]

AZSTARYS lowered mean SKAMP-C scores at **every time point measured throughout the day**[1]

Onset of effect was defined as the first time point showing a statistically significant difference vs placebo. Duration of effect was defined as the length of time between the first and last time points showing statistical significance vs placebo, or the last measured time point.[3]

Key secondary end point in patients aged 6 to 12 years: mean change from baseline in SKAMP-C scores at each time point[1]



Rapid onset in the early morning › **Sustained control of symptoms throughout the day** › **Smooth and gradual offset into the evening**

Study design: In the same study of 150 pediatric patients (aged 6-12 years) with ADHD after a 1-week treatment period, raters measured the change in SKAMP-C scores at each time point over 13 hours.[1] See additional study design details on page 10.

IMPORTANT SAFETY INFORMATION (continued)

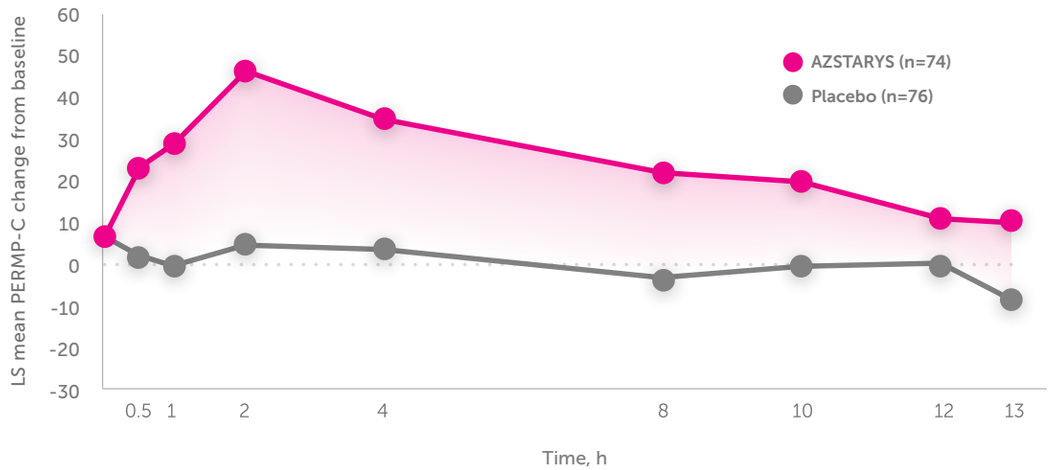
Warnings and Precautions (continued)

- Angle closure glaucoma associated with methylphenidate treatment has been reported. AZSTARYS-treated patients considered at risk for acute angle closure glaucoma should be evaluated by an ophthalmologist.
- Elevation of intraocular pressure (IOP) associated with methylphenidate treatment has been reported. Use of AZSTARYS with patients who have open-angle glaucoma or abnormally increased IOP should only be considered if the benefit of treatment outweighs the risk. Closely monitor AZSTARYS-treated patients with a history of abnormally increased IOP or open angle glaucoma.

Rapid 30-minute onset and extended 13-hour duration of symptom control[3]

Based on results from skill-adjusted math tests, AZSTARYS significantly improved PERMP-C scores, with more problems answered correctly at every time point measured[3,a]

Secondary end point in patients aged 6 to 12 years: mean change from baseline in PERMP-C scores at each time point[3,b]



Study design: In the same study of 150 pediatric patients (aged 6-12 years) with ADHD after a 1-week treatment period, raters also calculated patients' attention and behavior in a laboratory classroom setting over 13 hours using the PERMP rating scale.[1,3] See additional study design details on page 10.

PERMP-C, Permanent Product Measure of Performance-Correct.

[a]Based on change from baseline vs placebo.[3]

[b]Predose Visit 5 as baseline; statistical significance demonstrated at hours 0.5, 1, 2, 4, 8, 10, and 13 ($P<.001$), and hour 12 ($P=.01$), until the last time point of the classroom day.[3]

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- CNS stimulants, including methylphenidate, have been associated with the onset or exacerbation of motor and verbal tics. Worsening of Tourette's syndrome has also been reported. Before initiating AZSTARYS, assess family history and clinically evaluate patients for tics or Tourette's syndrome. Regularly monitor AZSTARYS-treated patients for the emergence or worsening of tics or Tourette's syndrome, and discontinue treatment if clinically appropriate.

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Safety in patients with ADHD

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with those of other drugs and may not reflect the rates observed in clinical practice.

Clinical trial experience with other MPH products in patients with ADHD[1]

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.

Safety profile similar to other MPHs[3]

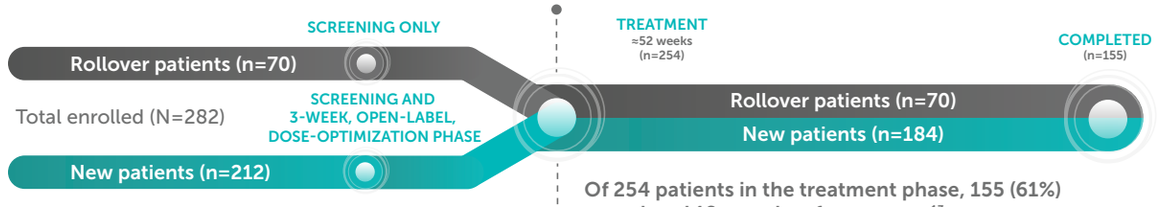
Incidence of TEAEs occurring in ≥2% of patients aged 6 to 12 years in any treatment group in a placebo-controlled study of AZSTARYS[9]

	Open-label dose-optimization phase (3 weeks)	**Randomized treatment phase** (1 week)	
Preferred term	**AZSTARYS (N=155),** n (%)	**AZSTARYS (N=74),** n (%)	**Placebo (N=76),** n (%)
Any TEAE	104 (67.1)	23 (31.1)	11 (14.5)
Decreased appetite	38 (24.5)	0 (0)	0 (0)
Insomnia	24 (15.5)	2 (2.7)	1 (1.3)
Affect lability	18 (11.6)	1 (1.4)	1 (1.3)
Upper abdominal pain	15 (9.7)	3 (4.1)	1 (1.3)
Headache	12 (7.7)	4 (5.4)	1 (1.3)
Irritability	12 (7.7)	0 (0)	0 (0)
Vomiting	6 (3.9)	1 (1.4)	1 (1.3)
Upper respiratory tract infection	6 (3.9)	2 (2.7)	4 (5.3)
Dizziness	4 (2.6)	0 (0)	0 (0)
Fatigue	4 (2.6)	0 (0)	0 (0)

TEAE, treatment-emergent adverse event.

Long-term safety and efficacy of **AZSTARYS**

The safety and efficacy of AZSTARYS were assessed in a long-term, multicenter, open-label, safety study over 12 months in children with ADHD aged 6 to 12 years.[1,13]



Eligible patients were either **rolled over after completing the AZSTARYS pivotal trial** or were new.[13]

Of 254 patients in the treatment phase, 155 (61%) completed 12 months of treatment.[13]

Out of the 282 total enrolled patients,
- 11 (3.9%) discontinued due to AEs
- 2 (0.7%) discontinued due to lack of efficacy

Primary end points: The occurrence of TEAEs assessed after the first dose of AZSTARYS and at the end of treatment.[9,13]

Secondary end points: Efficacy as measured by the ADHD-RS-5 and CGI[a] scales at each visit.[9,13]

Limitations of this study include the open-label nature of the study design and the lack of placebo or a comparator product. There may also be a selection bias during the course of the 12-month treatment duration. Patients who experienced lack of efficacy did discontinue from the study; therefore, efficacy assessments at latter time points may be affected in part by this selection bias.[13]

No conclusions can be made regarding additional or further long-term efficacy.[13]

ADHD-RS-5, Attention Deficit/Hyperactivity Disorder Rating Scale-Fifth Edition; AE, adverse event; CGI, Clinical Global Impressions.
[a]Results not included in this brochure.

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 decreased appetite, decreased weight, nausea, abdominal pain, dyspepsia, vomiting, insomnia, anxiety, affect lability, irritability, dizziness, increased blood pressure, and tachycardia.

Drug Interactions

- Adjust dosage of antihypertensive drug as needed. Monitor blood pressure.

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TEAEs observed during the open-label safety study were similar to other MPH stimulant therapies[13]

TEAEs in ≥5% of patients aged 6 to 12 years in the treatment phase for up to 12 months[13]

TEAE	AZSTARYS (N=238), n (%)
Any TEAE	**143 (60.1)**
Decreased appetite	**44 (18.5)**
Upper respiratory tract infection	**23 (9.7)**
Nasopharyngitis	**19 (8.0)**
Decreased weight	**18 (7.6)**
Irritability	**16 (6.7)**
Increased weight	**12 (5.0)**
Insomnia	**12 (5.0)**

Because of the open-label, uncontrolled design of the long-term safety study, the reported adverse reaction rates cannot be assessed in terms of a causal relationship to AZSTARYS.[1]

Study design: From the long-term, multicenter, open-label, safety study conducted over 12 months in patients aged 6 to 12 years.[13] See additional study design details on page 15.

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.

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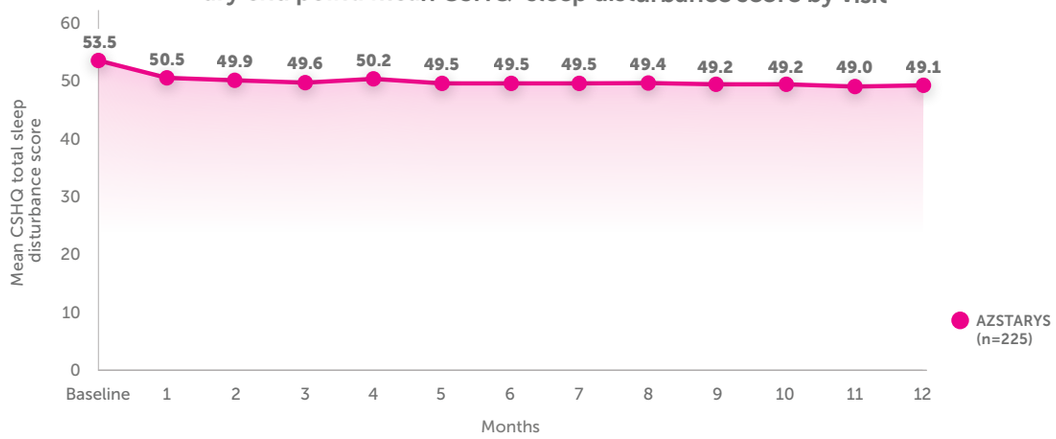
Effect on sleep behavior in patients treated with **AZSTARYS**[9]

Sleep behavior was assessed in the open-label long-term safety trial by using the modified CSHQ in patients aged 6 to 12 years[9,a]

- Before treatment, most patients reported sleep disturbances (mean CSHQ score: 53.5)
- Mean sleep quality scores improved slightly during treatment (mean CSHQ score at Month 12: 49.1)

Secondary end point: mean CSHQ[a] sleep disturbance score by visit[9,b]



Due to the open-label study design, conclusions and significance cannot be extrapolated.[1]

Study design: From the long-term, multicenter, open-label, safety study conducted over 12 months in patients aged 6 to 12 years.[13] See additional study design details on page 15.

CSHQ, Children's Sleep Habits Questionnaire.

[a]The modified CSHQ (a 33-item parent questionnaire) is used to assess sleep behavior in children. Each item is rated on a 3-point scale of usually, sometimes, and rarely. Lower scores indicate improvement. The clinical cutoff score (boundary between the group with sleep disorders and the general population) is ≥41.[9]

[b]The data were evaluated using the efficacy population (n=225).[9]

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 in patients treated 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.

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

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Effect on weight and height in patients treated with **AZSTARYS**[1]

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

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

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.

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.

Study design: From the long-term, multicenter, open-label, safety study conducted over 12 months in patients aged 6 to 12 years.[13] See additional study design details on page 15.

[a]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.[1]

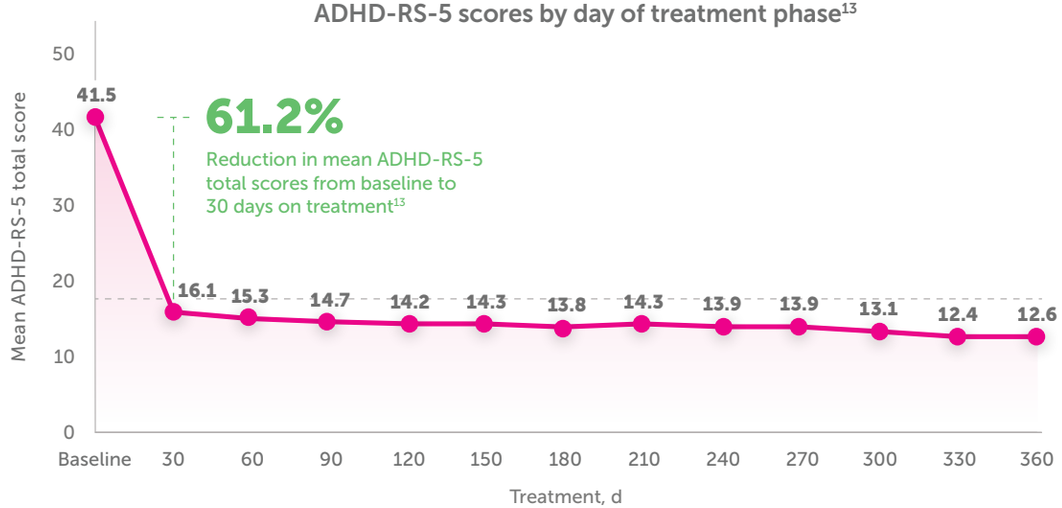
IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions

- Sudden death has been reported in patients with structural cardiac abnormalities or other serious cardiac disease who were treated with CNS stimulants at the recommended ADHD dosage. Avoid AZSTARYS use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery disease, or other serious cardiac disease.
- CNS stimulants cause an increase in blood pressure and heart rate. Monitor all AZSTARYS-treated patients for hypertension and tachycardia.
- *Exacerbation of Pre-existing Psychosis*: CNS stimulants 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*: CNS stimulants may induce a mixed mood/manic episode in patients with bipolar disorder. Prior to initiating AZSTARYS 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*: CNS stimulants at the recommended dosage may cause psychotic or manic symptoms (e.g., hallucinations, delusional thinking, or mania) in patients without a history of psychotic illness or mania. Consider discontinuing AZSTARYS if symptoms occur.

>60% reduction in ADHD-RS-5 score within 30 days and continuing over 12 months[13]

Secondary end point in patients aged 6 to 12 years: mean ADHD-RS-5 scores by day of treatment phase[13]



Due to the open-label study design, conclusions and significance cannot be extrapolated.[1]

Study design: From the long-term, multicenter, open-label, safety study conducted over 12 months in patients aged 6 to 12 years.[13] See additional study design details on page 15.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- Cases of painful and prolonged penile erections and priapism have been reported with methylphenidate use, in both adult and pediatric male patients. AZSTARYS-treated patients who develop abnormally sustained or frequent and painful erections should seek immediate medical attention.
- CNS stimulants, including AZSTARYS, are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; however, sequelae have included digital ulceration and/or soft tissue breakdown. Carefully observe patients during AZSTARYS treatment for digital changes. Further clinical evaluation may be appropriate for patients who develop signs or symptoms of peripheral vasculopathy.

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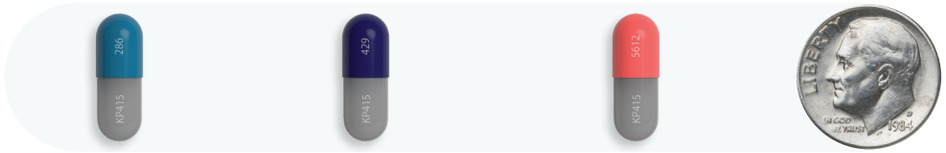
3 dosage strengths to meet the individual needs of your patients[1]



26.1 mg/
5.2 mg

**39.2 mg/
7.8 mg**

**Recommended
starting dose once daily**

52.3 mg/
10.4 mg

Capsules are
true to size.

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 years, the dosage may be increased to 52.3 mg/10.4 mg once daily, depending on response and tolerability
- The maximum daily dose is 52.3 mg/10.4 mg

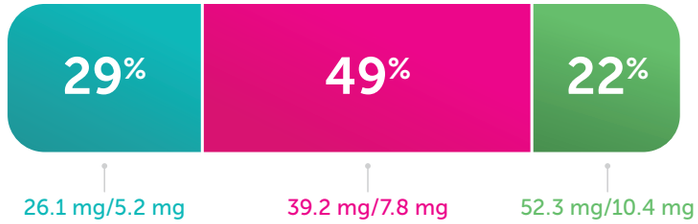
IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

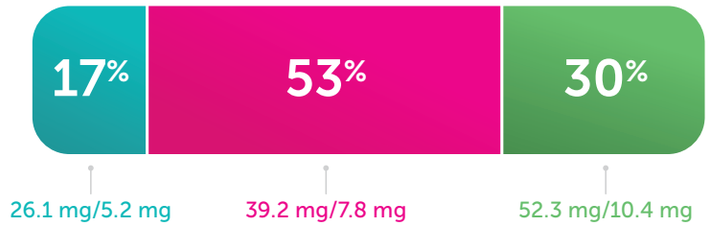
- CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients. Closely monitor height and weight at appropriate intervals in AZSTARYS-treated pediatric patients. Treatment may need to be interrupted in pediatric patients not growing or gaining weight as expected.
- Angle closure glaucoma associated with methylphenidate treatment has been reported. AZSTARYS-treated patients considered at risk for acute angle closure glaucoma should be evaluated by an ophthalmologist.
- Elevation of intraocular pressure (IOP) associated with methylphenidate treatment has been reported. Use of AZSTARYS with patients who have open-angle glaucoma or abnormally increased IOP should only be considered if the benefit of treatment outweighs the risk. Closely monitor AZSTARYS-treated patients with a history of abnormally increased IOP or open angle glaucoma.
- CNS stimulants, including methylphenidate, have been associated with the onset or exacerbation of motor and verbal tics. Worsening of Tourette's syndrome has also been reported. Before initiating AZSTARYS, assess family history and clinically evaluate patients for tics or Tourette's syndrome. Regularly monitor AZSTARYS-treated patients for the emergence or worsening of tics or Tourette's syndrome, and discontinue treatment if clinically appropriate.

Nearly half of **AZSTARYS** prescriptions are for the 39.2-mg/7.8-mg dose[9,a]

Pediatric and adolescent patients (aged <18 years)[b]



Adult patients[b]



[a]**Source: ADHD IQVIA XPD data from February 2022 to January 2023, with 79,502 prescriptions dispensed for pediatric and adolescent patients (aged <18 years) and 42,195 prescriptions dispensed for adult patients.**

[b]**Total prescriptions by AZSTARYS dosage strength.**

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 decreased appetite, decreased weight, nausea, abdominal pain, dyspepsia, vomiting, insomnia, anxiety, affect lability, irritability, dizziness, increased blood pressure, and tachycardia.

Drug Interactions

- Adjust dosage of antihypertensive drug as needed. Monitor blood pressure.

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Convenient once-daily dosing with 3 administration options[1]

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 sprinkled over 2 tablespoons of applesauce[a]

Daily morning dose may be taken **with or without food**

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

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, MISUSE, AND ADDICTION

AZSTARYS has a high potential for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Misuse and abuse of CNS stimulants, including AZSTARYS, can result in overdose and death and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.

Before prescribing AZSTARYS, assess each patient's risk for abuse, misuse, and addiction. Educate patients and their families about these risks, proper storage of the drug, and proper disposal of any unused drug. Throughout treatment, reassess each patient's risk and frequently monitor for signs and symptoms of abuse, misuse, and addiction.

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 in patients treated 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.

References: 1. AZSTARYS. Prescribing information. Corium, LLC; October 2023. **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.** 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 **4.** American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed. 2013. **5.** Centers for Disease Control and Prevention. Data and statistics about ADHD. Accessed May 24, 2023. https://www.cdc.gov/ncbddd/adhd/data.html **6.** Sibley MH, Swanson JM, Arnold LE, et al; for the MTA Cooperative Group. Defining ADHD symptom persistence in adulthood: optimizing sensitivity and specificity. *J Child Psychol Psychiatry*. 2017;58(6):655-662. doi:10.1111/jcpp.12620 **7.** Smalley SL, McGough JJ, Del'Homme M, et al. Familial clustering of symptoms and disruptive behaviors in multiplex families with attention-deficit/hyperactivity disorder. *J Am Acad Child Adolesc Psychiatry*. 2000;39(9):1135-1143. doi:10.1097/00004583-200009000-00013 **8.** Takeda T, Stotesbery K, Power T, et al. Parental ADHD status and its association with proband ADHD subtype and severity. *J Pediatr*. 2010;157(6):995-1000.e1. doi:10.1016/j.jpeds.2010.05.053 **9.** Data on file. Corium, LLC. **10.** 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:10.108017425255.2019.1675636 **11.** 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 **12.** 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 **13.** Childress AC, Marraffino A, Cutler AJ, Oh C, Brams MN. Safety and tolerability of serdexmethylphenidate/dexmethylphenidate capsules in children with attention-deficit/hyperactivity disorder: a 12-month, open-label safety study. *J Child Adolesc Psychopharmacol*. 2023;33(2):51-58. doi:10.1089/cap.2022.0076 **14.** Weiss M, Childress A, Nordbrock E, Adjei AL, Kupper RJ, Mattingly G. Characteristics of ADHD symptom response/remission in a clinical trial of methylphenidate extended release. *J Clin Med*. 2019;8(4):461. doi:10.3390/jcm8040461

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

$0 for their **first prescription** for eligible patients[a]

For refills, patients pay

$25 if their insurance **covers AZSTARYS** **OR** **$50** if their insurance **does not cover AZSTARYS**

Patients or their caregivers can call **1-800-910-8432** for information about CoriumCares™ support.

Scan the QR code or visit **AZSTARYS-pro.com** to learn more about savings and support

[a]Restrictions may apply. See Terms and Conditions at **AZSTARYS.com**.

IMPORTANT SAFETY INFORMATION (continued)

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