Once-daily dosing and administration with AZSTARYS®

Available in 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

The capsules are the same size across the 3 dosage strengths—slightly smaller than a dime.

Graphic is for comparative purposes only. Not actual size.

3 flexible administration options for the morning routine[1]

Swallow the capsule whole

or

Sprinkle the capsule contents into water[a]

or

Sprinkle the capsule contents onto applesauce[a]

AZSTARYS may be taken with or without food[1]

[a]The capsule contents may be sprinkled into 2 oz (50 mL) of water or 2 tablespoons of applesauce. 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 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**

azstarys® CII

serdexmethylphenidate and dexmethylphenidate

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

Please see additional Important Safety Information on next page and click here or scan the QR code for Full Prescribing Information, including Boxed WARNING.

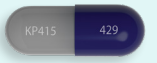
Dose optimization with AZSTARYS

In a clinical study of patients with ADHD aged 6 to 12 years, most patients were optimized on higher doses[1,2,a]

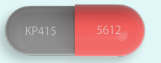
At the end of the dose-optimization phase[2]

93.5% of patients were optimized to the 2 higher doses of AZSTARYS

3.2%[b]
were optimized to
26.1 mg/5.2 mg



44.5%[b]
were optimized to
39.2 mg/7.8 mg



49.0%[b]
were optimized to
52.3 mg/10.4 mg

Approximately 60% of patients had no prior use of ADHD medications.[2]

AE, adverse event.

[a]The randomized, double-blind, placebo-controlled, parallel-group, analog classroom study included pediatric patients with ADHD aged 6 to 12 years (mean, 9 years). During the open-label dose-optimization phase (3 weeks), 155 patients were started on AZSTARYS 39.2 mg/7.8 mg once daily in the morning. 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) based on tolerability and best individual response in the opinion of the investigator.[1,2]

[b]The percentage of patients optimized does not add to 100% because 5 patients dropped out of the dose-optimization phase (4 due to AEs and 1 failed to meet randomization criteria). The percentages here are calculated based on a total population of 155 patients.[2]

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

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

Dosing AZSTARYS: Total daily d-MPH HCl from the IR d-MPH and SDX prodrug[1]

Recommended starting dose once daily

39.2 mg/7.8 mg

SDX — IR d-MPH

Total d-MPH HCl per dose

AZSTARYS (SDX/d-MPH)	Combined molar dose over the day (d-MPH HCl)
26.1 mg/5.2 mg	20 mg
39.2 mg/7.8 mg	30 mg
52.3 mg/10.4 mg	40 mg

The IR d-MPH plus the active d-MPH produced from the SDX conversion results in the combined molar dose for each dosage strength.

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

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.
- 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.
- 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.

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azstarys® (II)

serdexmethylphenidate and dexmethylphenidate

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Starting patients on AZSTARYS[1]

If switching from another treatment, discontinue that treatment and titrate with AZSTARYS using the titration schedule below.

Starting AZSTARYS

39.2 mg/7.8 mg
recommended once daily

Titration after 1 week, if needed

Increase
to **52.3 mg/10.4 mg**
(maximum recommended dose)
for patients aged 6 years and older

Decrease
to **26.1 mg/5.2 mg**
for patients aged 6 to 12 years

Switching from other MPH products

Do not substitute AZSTARYS for other MPH products on a milligram-per-milligram basis because these products have different PK profiles from AZSTARYS and may have different MPH base composition.

Copay savings may be available. Visit AZSTARYS-pro.com to learn more

MPH, methylphenidate; PK, pharmacokinetic.

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.

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.

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

References: 1. AZSTARYS. Prescribing information. Corium Inc; 2021. **2.** Data on file; Corium Inc.

Corium

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