

Helps control ADHD symptoms from morning to evening.

What is AZSTARYS?

AZSTARYS is a central nervous system (CNS) stimulant prescription medicine for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in people 6 years of age and older. AZSTARYS may help increase attention and decrease impulsiveness and hyperactivity in people 6 years of age and older with ADHD.

It is not known if AZSTARYS is safe and effective in children younger than 6 years of age.

IMPORTANT SAFETY INFORMATION

Abuse, misuse, and addiction. AZSTARYS has a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of AZSTARYS, other methylphenidate containing medicines, and amphetamine containing medicines, can lead to overdose and death. The risk of overdose and death is increased with higher doses of AZSTARYS or when it is used in ways that are not approved, such as snorting or injection.

- Your healthcare provider (HCP) should check you or your child's risk for abuse, misuse, and addiction before starting treatment with AZSTARYS.
 Tell your HCP if you or your child have ever abused or been dependent on alcohol, prescription medicines, or street drugs.
- AZSTARYS may lead to physical dependence after prolonged use, even if taken as directed by your HCP.
- Do not give AZSTARYS to anyone else because it may cause death or harm them. Keep AZSTARYS in a safe place to protect it from theft and properly dispose of any unused medicine.

AZSTARYS is a federally controlled substance (CII) because it contains dexmethylphenidate that can be a target for people who abuse prescription medicines or street drugs.

Please see additional Important Safety Information throughout and <u>Full Prescribing Information</u> and <u>Medication Guide</u>.



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

Discover what makes **AZSTARYS** different

AZSTARYS is pronounced az-star'-is

AZSTARYS has 2 forms of medicine in 1 capsule

Dexmethylphenidate

(deks-meth-uhl-fen-uh-date), or d-MPH

An immediate-release medicine that kicks in quickly

Serdexmethylphenidate

(sur-deks-meth-uhl-fen-uh-date), or SDX

A different way to provide continuous medicine throughout the day

Talk with your child's doctor to see if AZSTARYS may be the right treatment.



Visit **AZSTARYS.com** to learn more.

IMPORTANT SAFETY INFORMATION (continued) Who should not take AZSTARYS?

Do not take AZSTARYS if you or your child are:

- allergic to serdexmethylphenidate, methylphenidate, or any of the ingredients in AZSTARYS
- taking or have stopped taking within the past 14 days a medicine used to treat depression called a monoamine oxidase inhibitor (MAOI).

AZSTARYS is designed to help in 3 ways, from morning to evening



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- Risks for people with serious cardiac disease. Sudden death has happened in people who have heart defects or other serious heart disease. Your HCP should check you or your child carefully for heart problems before starting treatment with AZSTARYS. Tell your HCP if you or your child have any heart problems, heart disease, or heart defects. Call your HCP or go to the nearest hospital emergency room right away if you or your child have any signs of heart problems such as chest pain, shortness of breath, or fainting during treatment with AZSTARYS.
- Increased blood pressure and heart rate. Your HCP should check you or your child's blood pressure and heart rate regularly during treatment with AZSTARYS.
- Mental (psychiatric) problems, including: new or worse behavior and thought problems, new or worse bipolar illness, new psychotic symptoms (such as hearing voices, or seeing or believing things that are not real), or new manic symptoms. Tell your HCP about any mental problems you or your child have, or about a family history of suicide, bipolar illness, or depression. Call your HCP right away if you or your child have any new or worsening mental symptoms

or problems during treatment with AZSTARYS, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

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What **AZSTARYS** does

AZSTARYS helps control ADHD symptoms throughout the day

AZSTARYS may improve:



Attention

For example:

Finishing tasks, keeping track of time, or following directions

Actor portrayal



Hyperactivity

For example:

Sitting still, playing quietly, or staying seated during class





Impulsiveness

For example:

Taking turns, standing in line, or waiting for permission to use other people's things

Actor portrayals.

IMPORTANT SAFETY INFORMATION (continued) AZSTARYS may cause serious side effects, including: (continued)

- Painful and prolonged erections (priapism). Priapism has happened in males who take products that contain methylphenidate. If you or your child develop priapism, get medical help right away.
- Circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon). Tell your HCP if you or your child have numbness, pain, skin color change, or sensitivity to temperature in the fingers or toes. Call your HCP right away if you or your child have any signs of unexplained wounds appearing on fingers or toes during treatment with AZSTARYS.
- Slowing of growth (height and weight) in children. Children should have their height and weight checked often during treatment with AZSTARYS. AZSTARYS treatment may be stopped if your child is not growing or gaining weight.

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A study was done to test how AZSTARYS affected ADHD symptoms in children. The study included 150 children with ADHD aged 6 to 12 years. At different times during the day, the children's behavior was assessed.

- About half of the children received AZSTARYS
- The others received a sugar pill (also called a *placebo*)
- All of the children spent a **13-hour day** in a mock classroom

Children who took AZSTARYS

On average, their ADHD symptoms improved

Children who took placebo
On average, their ADHD symptoms

worsened

IMPORTANT SAFETY INFORMATION (continued)

AZSTARYS may cause serious side effects, including: (continued)

- Eye problems (increased pressure in the eye and glaucoma). Tell your HCP if you or your child have eye problems, including increased pressure in your eye, glaucoma, or problems with your close-up vision (farsightedness). Call your HCP right away if you or your child develop changes in your vision, eye pain, swelling, or redness.
- New or worsening tics or worsening Tourette's syndrome. Tell your HCP if you or your child get any new or worsening tics or worsening

Tourette's syndrome during treatment with AZSTARYS.

Please see additional Important Safety Information throughout and <u>Full Prescribing Information</u> and <u>Medication Guide</u>.



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How to take **AZSTARYS**

Take AZSTARYS exactly as prescribed

There are different options for taking AZSTARYS as part of the morning routine



Swallow whole

An AZSTARYS capsule can be swallowed whole with water or other liquids.

____ or ____



Sprinkle into water

The capsule can be opened and its contents can be sprinkled into 2 ounces (50 mL) of water.

____ or ___



Sprinkle onto applesauce

The contents can be sprinkled onto 2 tablespoons of applesauce.

All of the water or applesauce mixture should be swallowed within 10 minutes. **Do not** store the water or applesauce mixture.



IMPORTANT SAFETY INFORMATION (continued)

AZSTARYS may cause serious side effects, including: (continued)

Before taking AZSTARYS, tell your HCP about all medical conditions including if you or your child are pregnant or plan to become pregnant, because it is not known if AZSTARYS will harm the unborn baby, or are breastfeeding or plan to breastfeed, as AZSTARYS passes into breast milk.

Tell your HCP about all the medicines you or your child take, especially if you or your child take blood pressure medicines (anti-hypertensive). Do not start any new medicine during treatment with AZSTARYS without talking to your HCP first.

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How big is the AZSTARYS capsule?

- The AZSTARYS capsule is slightly smaller than a dime
- AZSTARYS comes in 3 dosage strengths
 - Each dosage strength is a different color
 - All the capsules are the same size



26.1 mg/ 5.2 mg



39.2 mg/ 7.8 mg



52.3 mg/ 10.4 mg



Capsules are not true to size

IMPORTANT SAFETY INFORMATION (continued) What are the most common side effects of AZSTARYS?

The most common side effects of AZSTARYS include:

- decreased appetite
- nausea
- indigestion
- weight loss
- dizziness
- mood swings
- increased blood pressure

These are not all the possible side effects of AZSTARYS. Call your HCP for medical advice about side effects.

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- trouble sleeping
- vomiting
- stomach pain
- anxiety

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- irritability
- increased heart rate



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IMPORTANT SAFETY INFORMATION (continued)

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• dizziness

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- trouble sleeping
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You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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AZSTARYS is the first and only ADHD treatment of its kind

 AZSTARYS helps control ADHD symptoms throughout the day

• Once-daily AZSTARYS can be swallowed whole or sprinkled into water or onto applesauce

 Copay savings may be available.* Scan the QR code below or visit <u>AZSTARYS.com</u> to learn more



Scan the QR code using your phone's camera to see savings information.

*Eligibility required. See Terms and Conditions at AZSTARYS.com.

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