

MEDICATION GUIDE
AZSTARYS® (az star' is)
(serdexmethylphenidate and dexamethylphenidate) capsules, CII

What is the most important information I should know about AZSTARYS?

AZSTARYS may cause serious side effects, including:

- **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 should check you or your child's risk for abuse, misuse, and addiction before starting treatment with AZSTARYS and will monitor you or your child during treatment.
- AZSTARYS may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
- Do not give AZSTARYS to anyone else. See **"What is AZSTARYS?"** for more information.
- Keep AZSTARYS in a safe place and properly dispose of any unused medicine. See **"How should I store AZSTARYS?"** for more information.

- Tell your healthcare provider if you or your child have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

- **Risks for people with serious heart disease.** Sudden death has happened in people who have heart defects or other serious heart disease.
Your healthcare provider should check you or your child carefully for heart problems before starting treatment with AZSTARYS. Tell your healthcare provider if you or your child have any heart problems, heart disease, or heart defects.

Call your healthcare provider 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 healthcare provider 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 healthcare provider about any mental problems you or your child have, or about a family history of suicide, bipolar illness, or depression.

Call your healthcare provider 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.

What is AZSTARYS?

AZSTARYS is a central nervous system stimulant prescription medicine used 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.

AZSTARYS is not recommended for use in children under 6 years of age with ADHD.

AZSTARYS is a federally controlled substance (CII) because it contains dexamethylphenidate that can be a target for people who abuse prescription medicines or street drugs. Keep AZSTARYS in a safe place to protect it from theft. Never give your AZSTARYS to anyone else because it may cause death or harm them. Selling or giving away AZSTARYS may harm others and is against the law.

Do not take AZSTARYS if you or your child are:

- allergic to serdexmethylphenidate, methylphenidate, or any of the ingredients in AZSTARYS. See the end of this Medication Guide for a complete list of 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).

Before taking AZSTARYS, tell your healthcare provider about all medical conditions, including if you or your child:

- have heart problems, heart disease, heart defects, or high blood pressure
- have mental problems including psychosis, mania, bipolar illness, or depression, or has a family history of suicide, bipolar illness, or depression
- have circulation problems in fingers or toes
- have eye problems, including increased pressure in your eye, glaucoma, or problems with your close-up vision (farsightedness)
- have or had repeated movements or sounds (tics) or Tourette's syndrome, or have a family history of tics or Tourette's syndrome
- are pregnant or plans to become pregnant. It is not known if AZSTARYS will harm the unborn baby.
 - There is a pregnancy registry for females who are exposed to ADHD medications, including AZSTARYS, during pregnancy. The purpose of the registry is to collect information about the health of females exposed to AZSTARYS and their baby. If you or your child becomes pregnant during treatment with AZSTARYS, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychostimulants at 1-866-961-2388.
- are breastfeeding or plans to breastfeed. AZSTARYS passes into breast milk. Talk to your healthcare provider about the best way to feed the baby during treatment with AZSTARYS.

Tell your healthcare provider about all of the medicines that you or your child take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

AZSTARYS and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be adjusted during treatment with AZSTARYS. Your healthcare provider will decide whether AZSTARYS can be taken with other medicines.

Especially tell your healthcare provider if you or your child takes: blood pressure medicines (anti-hypertensive)

Know the medicines that you or your child take. Keep a list of the medicines with you to show your healthcare provider and pharmacist. **Do not start any new medicine during treatment with AZSTARYS without talking to your healthcare provider first.**

How should AZSTARYS be taken?

- Take AZSTARYS exactly as prescribed.
- Your healthcare provider may change the dose if needed.
- Take AZSTARYS 1 time each day in the morning with or without food.
- AZSTARYS capsules may be swallowed whole with water or other liquids.
- If AZSTARYS capsules cannot be swallowed whole, the capsule may be opened and the entire contents sprinkled onto 2 tablespoonfuls of applesauce or into 2oz (50mL) of water.
 - Swallow all the applesauce or water mixture right away or within 10 minutes of mixing. **Do not** store applesauce or water and medicine mixture.

If you or your child take too much ASZTARYS, call your healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What are the possible side effects of AZSTARYS?

AZSTARYS may cause serious side effects, including:

- See “What is the most important information I should know about AZSTARYS?”
- **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).** Signs and symptoms may include:
 - fingers or toes may feel numb, cool, or painful
 - fingers or toes may change color from pale, to blue, to redTell your healthcare provider if you or your child have numbness, pain, skin color change, or sensitivity to temperature in the fingers or toes.
Call your healthcare provider 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 AZSTARYS. AZSTARYS treatment may be stopped if your child is not growing or gaining weight.
- **Eye problems (increased pressure in the eye and glaucoma).** Call your healthcare provider right away if you or your child develop changes in your vision or eye pain, swelling, or redness.
- **New or worsening tics or worsening Tourette’s syndrome.** Tell your healthcare provider if you or your child get any new or worsening tics or worsening Tourette’s syndrome during treatment with AZSTARYS.

The most common side effects of AZSTARYS include:

- decreased appetite
- nausea
- indigestion
- weight loss
- dizziness
- mood swings
- increased blood pressure
- trouble sleeping
- vomiting
- stomach pain
- anxiety
- irritability
- increased heart rate

These are not all the possible side effects of AZSTARYS.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store AZSTARYS?

- Store AZSTARYS in a safe place and in a tightly closed container at room temperature between 68°F to 77°F (20°C to 25°C).
- Dispose of remaining, unused, or expired AZSTARYS by a medicine take-back program at a U.S. Drug Enforcement Administration (DEA) authorized collection site. If no take-back program or DEA authorized collector is available, mix AZSTARYS with an undesirable, nontoxic substance such as dirt, cat litter, or used coffee grounds to make it less appealing to children and pets. Place the mixture in a container such as a sealed plastic bag and throw away AZSTARYS in the household trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

Keep AZSTARYS and all medicines out of the reach of children.

General information about the safe and effective use of AZSTARYS.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use AZSTARYS for a condition for which it was not prescribed. Do not give AZSTARYS to other people, even if they have the same symptoms that you have. It may harm them, and it is against the law. You can ask your healthcare provider or pharmacist for information about AZSTARYS that is written for healthcare professionals.

What are the ingredients in AZSTARYS?

Active ingredients: serdexmethylphenidate and dexmethylphenidate

Inactive ingredients: colloidal silicon dioxide, crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, talc, black iron oxide, titanium dioxide, FD&C Blue No. 1 (26/5.2 mg and 39/7.8 mg), FD&C Red No. 40 (39/7.8 mg and 52/10.4 mg), FD&C Yellow No. 6 (52/10.4 mg)

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For more information call 1-855-253-2407 or go to www.AZSTARYS.com