

MEDICATION GUIDE

AZSTARYS™ (az star' is)

(serdexmethylphenidate and dexmethylphenidate) capsules, CII

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

AZSTARYS can cause serious side effects, including:

- **Abuse and dependence.** AZSTARYS, other methylphenidate containing medicines, and amphetamines have a high chance for abuse and can cause physical and psychological dependence. Your healthcare provider should check you or your child for signs of abuse and dependence before and during treatment with AZSTARYS.
 - Tell your healthcare provider if you or your child have ever abused or been dependent on alcohol, prescription medicines, or street drugs.
 - Your healthcare provider can tell you more about the differences between physical and psychological dependence and drug addiction.
- **Heart-related problems, including:**
 - sudden death, stroke, and heart attack in adults
 - sudden death in children who have heart problems or heart defects
 - increased blood pressure and heart rate

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 defects, high blood pressure, or a family history of these.

Your healthcare provider should check you or your child's blood pressure and heart rate regularly during treatment with AZSTARYS.

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.

- **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.

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

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. Keep AZSTARYS in a safe place to protect it from theft. Never give 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 defects, 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
- 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 take:

- MAOIs
- 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.
- Your healthcare provider may sometimes stop AZSTARYS treatment for a while to check ADHD symptoms.

In case of poisoning, call your poison control center 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.

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 authorized collection sites such as retail pharmacies, hospital or clinic pharmacies, and law enforcement locations. If no take-back program or 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 (discard) AZSTARYS in the household trash.

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 was 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 1-800-910-8432 or go to www.AZSTARYS.com

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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