

MEDICATION GUIDE
ADZENYS ER (ad-ZEN-es EE-AR)
(amphetamine)
extended-release oral suspension, CII

What is the most important information I should know about ADZENYS ER?

ADZENYS ER can cause serious side effects, including:

• **Abuse and dependence.** ADZENYS ER, other amphetamine containing medicines, and methylphenidate 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 ADZENYS ER.

- 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 attacks in adults
- sudden death in children and adolescents 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 ADZENYS ER.

Tell your healthcare provider if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems.

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

Call your healthcare provider or go to the nearest hospital emergency room right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting during treatment with ADZENYS ER.

• **Mental (psychiatric) problems, including:**

- new or worse behavior and thought problems
- new or worse bipolar illness
- new psychotic symptoms (such as hearing voices, 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 ADZENYS ER, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

What is ADZENYS ER?

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

It is not known if ADZENYS ER is safe and effective in children under 6 years of age.

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

Do not take ADZENYS ER if you or your child are:

- allergic to amphetamine or any of the ingredients in ADZENYS ER. See the end of this Medication Guide for a complete list of ingredients in ADZENYS ER.
- taking or have taken within the past 14 days, a medicine used to treat depression called monoamine oxidase inhibitor (MAOI).

Before taking ADZENYS ER, tell your or your child's healthcare provider about all medical conditions, including if you or your child:

- have heart problems, heart defects, or high blood pressure
- have mental problems including psychosis, mania, bipolar illness, or depression, or have a family history of suicide
- have circulation problems in fingers and toes

Tell your doctor:

- if you or your child have kidney problems. Your doctor may lower the dose.
- if you or your child are pregnant or plan to become pregnant. It is not known if ADZENYS ER will harm your unborn baby. Tell your healthcare provider if you or your child become pregnant during treatment with ADZENYS ER.
 - There is a pregnancy registry for females who are exposed to ADZENYS ER during pregnancy. The purpose of the registry is to collect information about the health of females exposed to ADZENYS ER and their baby. If you or your child becomes pregnant during treatment with ADZENYS ER, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychostimulants at 1-866-961-2388.
- are breastfeeding or plan to breastfeed. ADZENYS ER passes into breast milk. You or your child should not breastfeed during treatment with ADZENYS ER.

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

Your healthcare provider will decide whether ADZENYS ER can be taken with other medicines. **Especially tell your healthcare provider if you or your child takes** medicine used to treat depression, including MAOIs.

Do not start any new medicine during treatment while taking ADZENYS ER without talking to your healthcare provider first.

How should I take ADZENYS ER?

- Take ADZENYS ER exactly as prescribed by your healthcare provider.
- Your healthcare provider may change the dose if needed.
- Take ADZENYS ER 1 time each day in the morning.
- ADZENYS ER can be taken with or without food. Do not add ADZENYS ER to food or mix with other liquids before taking.
- Shake the bottle of ADZENYS ER well before each dose.
- Use the oral dosing syringe or measuring device provided by your pharmacist to measure the prescribed dose of ADZENYS ER.
- Wash the oral dosing syringe or measuring device after each use.
- Replace the child-resistant bottle cap after each use.
- Your healthcare provider may sometimes stop ADZENYS ER treatment for a while to check ADHD symptoms.

If you or your child take(s) too much ADZENYS ER, call your **healthcare provider** or poison control center or go to the nearest hospital emergency room right away.

What should I avoid during treatment with ADZENYS ER?

You should avoid drinking alcohol during treatment with ADZENYS ER.

What are possible side effects of ADZENYS ER?

ADZENYS ER can cause serious side effects, including:

- See “**What is the most important information I should know about ADZENYS ER?**”
- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with ADZENYS ER. Your healthcare provider may stop treatment with ADZENYS ER if they are not growing or gaining weight as expected.
- **Circulation problems in fingers and toes (peripheral vasculopathy including Raynaud’s phenomenon).** Signs and symptoms may include:
 - fingers or toes may feel numb, cool, painful
 - fingers or toes may change from pale, to blue, to red

Tell your healthcare provider if you or your child have numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.

Call your healthcare provider right away if you or your child have any unexplained wounds appearing on fingers or toes during treatment with ADZENYS ER.

- **Serotonin Syndrome.** This problem may happen when ADZENYS ER is taken with certain other medicines and may be life threatening. **Call your healthcare provider or go to the nearest hospital emergency room if you have any of the following symptoms of serotonin syndrome:**
 - agitation, hallucinations, coma or other changes in mental status
 - sweating or fever
 - problems controlling your movements or muscle twitching
 - muscle stiffness or tightness
 - fast heartbeat
 - nausea vomiting or diarrhea
 - high or low blood pressure

The most common side effects of ADZENYS ER in children 6 to 12 years of age include:

- decreased appetite
- extreme mood change
- nausea
- problems sleeping
- vomiting
- fever
- stomach pain
- nervousness

The most common side effects of ADZENYS ER in children 13 to 17 years of age include:

- decreased appetite
- stomach pain
- nervousness
- problems sleeping
- weight loss

The most common side effects of ADZENYS ER in adults include:

- dry mouth
- nausea
- diarrhea
- decreased appetite
- anxiety
- weakness
- problems sleeping
- restlessness
- urinary tract infection
- headache
- dizziness
- weight loss
- fast heartbeat

These are not all the possible side effects of ADZENYS ER. 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 ADZENYS ER?

- Store ADZENYS ER at room temperature between 68°F to 77°F (20°C to 25°C).
- Store ADZENYS ER in a safe place, like a locked cabinet.
- Dispose of remaining, unused, or expired ADZENYS ER 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 ADZENYS ER 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 discard ADZENYS ER in the household trash.

Keep ADZENYS ER and all medicines out of the reach of children.

General information about the safe and effective use of ADZENYS ER

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

What are the ingredients in ADZENYS ER?

Active ingredients: amphetamine

Inactive ingredients: purified water, sorbitol, propylene glycol, xanthan gum, natural orange flavor, methacrylic acid and methyl methacrylate copolymer, sodium polystyrene sulfonate, vegetable oil, triethyl citrate, methylparaben, citric acid, sucralose, propylparaben, orange color (FD&C Yellow No. 6), and polyethylene glycol

Manufactured for Neos Therapeutics Brands, LLC, Grand Prairie, TX 75050.

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For more information about ADZENYS ER contact Neos Therapeutics, Inc. at 1-888-236-6816 or go to WWW.ADZENYSER.COM.

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

Issued: 9/2017
N00272

