

**MEDICATION GUIDE**  
**ADZENYS XR-ODT (add-ZEN-iss)**  
**(amphetamine)**  
**extended-release orally disintegrating tablets, CII**

**What is the most important information I should know about ADZENYS XR-ODT?**

**ADZENYS XR-ODT may cause serious side effects, including:**

- **Abuse, misuse, and addiction.** ADZENYS XR-ODT has a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of ADZENYS XR-ODT, other amphetamine containing medicines, and methylphenidate containing medicines, can lead to overdose and death. The risk of overdose and death is increased with higher doses of ADZENYS XR-ODT 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 ADZENYS XR-ODT and will monitor you or your child during treatment.
  - ADZENYS XR-ODT may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
  - Do not give ADZENYS XR-ODT to anyone else. See “**What is ADZENYS XR-ODT?**” for more information.
  - Keep ADZENYS XR-ODT in a safe place and properly dispose of any unused medicine. See “**How should I store ADZENYS XR-ODT?**” 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 ADZENYS XR-ODT. Tell your healthcare provider if you or your child has 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 has any signs of heart problems such as chest pain, shortness of breath, or fainting while taking ADZENYS XR-ODT.**

- **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 ADZENYS XR-ODT.

- **Mental (Psychiatric) problems:**

All Patients

- new or worse behavior and thought problems
- new or worse bipolar illness
- new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) 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 while taking ADZENYS XR-ODT, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.**

**What is ADZENYS XR-ODT?**

ADZENYS XR-ODT is a central nervous system (CNS) stimulant prescription medicine. **It is used for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD).** ADZENYS XR-ODT may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

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

**ADZENYS XR-ODT 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 XR-ODT in a safe place to prevent it from theft. Never give your ADZENYS XR-ODT to anyone else, because it may harm them. Selling or giving away ADZENYS XR-ODT may harm others and is against the law.

**Who should not take ADZENYS XR-ODT?**

**ADZENYS XR-ODT should not be taken if you or your child:**

- are allergic to amphetamine, or any of the ingredients in ADZENYS XR-ODT. See the end of this Medication Guide for a complete list of ingredients in ADZENYS XR-ODT.
- are taking or have taken within the past 14 days an anti-depression medicine called monoamine oxidase inhibitor or MAOI.

**What should I tell my healthcare provider before taking ADZENYS XR-ODT?**

**ADZENYS XR-ODT may not be right for you or your child. Before starting ADZENYS XR-ODT, tell your or your child's healthcare provider about all health conditions (or a family history of) including:**

- heart problems, heart disease, heart defects, or high blood pressure
- mental problems including psychosis, mania, bipolar illness, or depression
- circulation problems in fingers and toes

Tell your healthcare provider:

- if you or your child have kidney problems. Your healthcare provider may lower the dose.
- have or had repeated movements or sounds (tics) or Tourette's syndrome, or have a family history of tics or Tourette's syndrome.
- if you or your child are pregnant, or plan to become pregnant. It is not known if ADZENYS XR-ODT will harm your unborn baby.
- if you or your child is breastfeeding or plan to breastfeed. ADZENYS XR-ODT passes into breast milk. You should not breastfeed while you are taking ADZENYS XR-ODT.

**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 XR-ODT and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be adjusted while taking ADZENYS XR-ODT.

Your healthcare provider will decide whether ADZENYS XR-ODT can be taken with other medicines.

**Especially tell your healthcare provider if you or your child takes:**

- anti-depression medicines including MAOIs

Know the medicines that you or your child take. Keep a list of your medicines with you to show your healthcare provider and pharmacist.

**Do not start any new medicine while taking ADZENYS XR-ODT without talking to your healthcare provider first.**

**How should ADZENYS XR-ODT be taken?**

- Take ADZENYS XR-ODT exactly as prescribed. Your healthcare provider may adjust the dose until it is right for you or your child.
- Take ADZENYS XR-ODT 1 time each day in the morning.
  - Leave the tablet in the blister pack until you are ready to take or give it.
  - Use dry hands to open the blister pack.
  - Tear along the perforation, bend the blister where indicated and peel back the blister's labeled backing to take out the tablet. **Do not push the tablet through the foil.**
  - Place the tablet on the tongue.
  - Take ADZENYS XR-ODT as soon as you open the blister pack. The tablet will dissolve in your mouth (saliva) so that it can be swallowed.
  - Do not crush or chew.
- ADZENYS XR-ODT can be taken with or without food.
- Your healthcare provider may do regular checks of your or your child's blood, heart, and blood pressure while taking ADZENYS XR-ODT.
- Children should have their height and weight checked often while taking ADZENYS XR-ODT. ADZENYS XR-ODT treatment may be stopped if a problem is found during these check-ups.

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

**What should I avoid while taking ADZENYS XR-ODT?**

- drinking alcohol

**What are possible side effects of ADZENYS XR-ODT?****ADZENYS XR-ODT can cause serious side effects, including:**

- See **“What is the most important information I should know about ADZENYS XR-ODT?”** for information on reported heart and mental problems.
- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with ADZENYS XR-ODT. Your healthcare provider may stop your child's ADZENYS XR-ODT treatment if they are not growing or gaining weight as expected.
- **Circulation problems in fingers and toes** [Peripheral vasculopathy, including Raynaud's phenomenon]:
  - fingers or toes may feel numb, cool, painful
  - fingers or toes may change from pale, to blue, to redTell your healthcare provider if you have or your child has numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.  
**Call your healthcare provider right away if you have or your child has any unexplained wounds appearing on fingers or toes while taking ADZENYS XR-ODT.**
- **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 ADZENYS XR-ODT.

**Common side effects of ADZENYS XR-ODT include** decreased appetite and problems sleeping.

**Common side effects of ADZENYS XR-ODT in children 6 to 12 years of age also include:**

- |                       |            |
|-----------------------|------------|
| • stomach pain        | • nausea   |
| • nervousness         | • vomiting |
| • extreme mood change | • fever    |

**Common side effects of ADZENYS XR-ODT in children 13 to 17 years of age also include:**

- |                |               |
|----------------|---------------|
| • stomach pain | • weight loss |
|----------------|---------------|

**Common side effects of ADZENYS XR-ODT in adults also include:**

- |             |                            |
|-------------|----------------------------|
| • dry mouth | • fast heart beat          |
| • nausea    | • urinary tract infections |
| • dizziness | • weight loss              |
| • weakness  | • restlessness             |
| • headache  | • diarrhea                 |
| • anxiety   |                            |

Talk to your healthcare provider if you or your child have side effects that are bothersome or do not go away.

These are not all the possible side effects ADZENYS XR-ODT.

**Call your doctor for medical advice about side effects. You may report side effects to FDA at 1800-FDA-1088.**

**How should I store ADZENYS XR-ODT?**

- Store ADZENYS XR-ODT at room temperature between 68° F to 77° F (20° C to 25° C).
- Store ADZENYS XR-ODT in a safe place, like a locked cabinet.
- Store ADZENYS XR-ODT in the blister packaging until you are ready to take or give it.
- Store ADZENYS XR-ODT blister packages in the hard plastic travel case provided after removal from the carton.
- Dispose of remaining, unused, or expired ADZENYS XR-ODT 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 ADZENYS XR-ODT 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 ADZENYS XR-ODT in the household trash. Visit [www.fda.gov/drugdisposal](http://www.fda.gov/drugdisposal) for additional information on disposal of unused medicines.

**Keep ADZENYS XR-ODT and all medicines out of the reach of children.**

**General information about the safe and effective use of ADZENYS XR-ODT**

Medicines are sometimes prescribed for purposes other than those listed in the Medication Guide. Do not use ADZENYS XR-ODT for a condition for which it has not been prescribed. Do not give ADZENYS XR-ODT to other people, even if they have the same condition. It may harm them and it is against the law. This Medication Guide summarizes the most important information about ADZENYS XR-ODT. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about ADZENYS XR-ODT that is written for healthcare professionals. For more information about ADZENYS XR-ODT or to get a plastic travel case contact Neos Therapeutics, Inc. at 1-888-236-6816 or go to [www.adzenysxrodt.com](http://www.adzenysxrodt.com).

**What are the ingredients in ADZENYS XR-ODT?**

**Active Ingredients:** Amphetamine

**Inactive Ingredients:** Mannitol, Crospovidone, Microcrystalline Cellulose, Methacrylic Acid, Sodium Polystyrene Sulfonate, Citric Acid, Fructose, Orange Flavor, Colloidal Silicon Dioxide, Triethyl Citrate, Sucralose, Lake Blend Orange, Magnesium Stearate, and Polyethylene Glycol 3350.

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

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