

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 is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep ADZENYS XR-ODT in a safe place to prevent misuse and abuse. Selling or giving away ADZENYS XR-ODT may harm others and is against the law.

Tell your doctor if you or your child has ever abused or been dependent on alcohol, prescription medicines, or street drugs.

ADZENYS XR-ODT is a stimulant medicine. Some patients have had the following problems when taking stimulant medicines.

1. Heart-related problems:

- **sudden death in patients who have heart problems or heart defects**
- **sudden death, stroke and heart attack in adults**
- **increased blood pressure and heart rate**

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

Your doctor should check you or your child carefully for heart problems before starting ADZENYS XR-ODT.

Your doctor should check you or your child's blood pressure and heart rate regularly during treatment with ADZENYS XR-ODT.

Call your doctor 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.

2. 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 doctor about any mental problems you or your child have, or about a family history of suicide, bipolar illness, or depression.

Call your doctor 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.

3. 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 red**

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

Call your doctor right away if you have or your child has any unexplained wounds appearing on fingers or toes while taking ADZENYS XR-ODT.

What is ADZENYS XR-ODT?

ADZENYS XR-ODT is a central nervous system 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.

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 doctor 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 doctor about all health conditions (or a family history of) including:

- heart problems, heart defects, or high blood pressure
- mental problems including psychosis, mania, bipolar illness, or depression
- 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 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 doctor 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 doctor will decide whether ADZENYS XR-ODT can be taken with other medicines.

Especially tell your doctor 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 doctor and pharmacist.

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

How should ADZENYS XR-ODT be taken?

- Take ADZENYS XR-ODT exactly as prescribed. Your doctor 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 doctor may sometimes stop ADZENYS XR-ODT treatment for a while to check ADHD symptoms.
- Your doctor 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(s) too much ADZENYS XR-ODT, call your doctor or poison control center at 1-800-222-1222 right away, or go to the nearest hospital emergency room.

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

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 • extreme mood change • vomiting
- nervousness • nausea • 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 • headache • weight loss
- nausea • anxiety • restlessness
- dizziness • fast heart beat • diarrhea
- weakness • urinary tract infections

Talk to your doctor 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. Ask your doctor or pharmacist for more information.

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 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 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 discard ADZENYS XR-ODT in the household trash.

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 doctor. You can ask your doctor or pharmacist for information about ADZENYS XR-ODT that was 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.

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.

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

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