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2. Adzenys XR-ODT

Adzenys XR-ODT

Generic name: amphetamine [am-FET-a-meen]

Brand names: Adzenys XR-ODT, Amphetamine Sulfate, Dyanavel XR, Evekeo, Evekeo ODT

Drug class: CNS stimulants



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What is Adzenys XR-ODT?

Adzenys XR-ODT is a stimulant medicine that is used to treat attention deficit hyperactivity disorder (ADHD) in children. Some brands of amphetamine are for children 6 years and older. **Evekeo** can be used in children as young as 3 years old.

Evekeo is also used to treat narcolepsy in adults and children at least 6 years old, or obesity in adults and children at least 12 years old who have not lost weight with diets or other treatments.

Evekeo ODT is used only to treat ADHD in children at least 6 years old.

Adzenys XR-ODT may also be used for purposes not listed in this medication guide.

Adzenys XR-ODT side effects

Get emergency medical help if you have **signs of an allergic reaction:** hives; difficult breathing; swelling of your face, lips, tongue, or throat.

Adzenys XR-ODT may cause serious side effects. Call your doctor at once if you have:

- signs of heart problems--chest pain, trouble breathing, feeling like you might pass out;
- signs of psychosis--hallucinations (seeing or hearing things that are not real), new behavior problems, aggression, hostility, paranoia;
- signs of circulation problems--numbness, pain, cold feeling, unexplained wounds, or skin color changes (pale, red, or blue appearance) in your fingers or toes;
- a seizure (convulsions);
- muscle twitches (tics);
- · increased blood pressure or heart rate; or
- · changes in your vision.

Seek medical attention right away if you have symptoms of serotonin syndrome, such as: agitation, hallucinations, fever, sweating, shivering, fast heart rate, muscle stiffness, twitching, loss of coordination, nausea, vomiting, or diarrhea.

Adzenys XR-ODT can affect growth in children. Tell your doctor if your child is not growing at a normal rate while using Adzenys XR-ODT.

Common side effects of Adzenys XR-ODT may include:

- · increased heart rate;
- mood changes, anxiety, feeling restless or nervous;
- · trouble sleeping;
- dry mouth, stomach pain, nausea, vomiting, diarrhea, constipation;
- · loss of appetite, weight loss;
- sexual problems (impotence in males);
- · headache, dizziness; or
- · itching.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Adzenys XR-ODT side effects (more detail)

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Warnings

Stimulants have caused stroke, heart attack, and sudden death in people with high blood pressure, heart disease, or a heart defect.

Do not use Adzenys XR-ODT if you have used an MAO inhibitor in the past 14 days. A dangerous drug interaction could occur. MAO inhibitors include isocarboxazid, linezolid, methylene blue injection, phenelzine, and tranylcypromine.

Adzenys XR-ODT may be habit-forming. **Misuse can cause addiction, overdose, or death.** Keep the medication where others cannot get to it. Selling or giving away this medicine is against the law.

Call your doctor right away if you have: **signs of heart problems**--chest pain, feeling light-headed or short of breath; **signs of psychosis**--paranoia, aggression, new behavior problems, seeing or hearing things that are not real; or **signs of circulation problems**--numbness, pain, cold feeling, unexplained wounds, or skin color changes (pale, red, or blue appearance) in your fingers or toes.

This medicine can affect the results of certain medical tests. Tell any doctor who treats you that you are using Adzenys XR-ODT.

Before taking this medicine

You should not use Adzenys XR-ODT if you are allergic to any stimulant medicine, or if you have used an MAO inhibitor in the past 14 days, such as isocarboxazid, linezolid, methylene blue injection, phenelzine, or tranylcypromine.

You may not be able to use Adzenys XR-ODT if you have:

- chest pain or breathing problems caused by heart disease;
- · hardening of the arteries;
- moderate to severe high blood pressure;
- · overactive thyroid;
- · a history of drug abuse; or
- if you are agitated.

Stimulants have caused stroke, heart attack, and sudden death in certain people. Tell your doctor if you have:

heart problems or a congenital heart defect;

- · high blood pressure; or
- · a family history of heart disease or sudden death.

Tell your doctor if you or anyone in your family has had:

- depression, mental illness, bipolar disorder, psychosis, or suicidal thoughts or actions;
- problems with drug or alcohol abuse;
- motor tics (muscle twitches) or Tourette's syndrome;
- a thyroid disorder;
- seizures or epilepsy;
- an abnormal brain wave test (electroencephalogram; EEG);
- coronary artery disease (clogged arteries);
- blood circulation problems in the hands or feet; or
- · kidney disease.

Tell your doctor if you are pregnant or plan to become pregnant. Taking Adzenys XR-ODT during pregnancy may increase the risk of premature birth or low birth weight. If you are pregnant, your name may be listed on a pregnancy registry to track the effects of amphetamine on the baby.

Do not breastfeed

How should I take Adzenys XR-ODT?

Follow all directions on your prescription label and read all medication guides or instruction sheets. Your doctor may occasionally change your dose. Use the medicine exactly as directed.

Adzenys XR-ODT may be habit-forming. **Misuse can cause addiction, overdose, or death. Keep the medicine in a safe place where others cannot get to it.** Selling or giving away Adzenys XR-ODT is against the law.

Do not use this medicine more often than prescribed.

You may take Adzenys XR-ODT with or without food.

Dynavel XR tablets may be chewed if not able to swallow.

Shake the oral suspension (liquid). Measure a dose with the supplied measuring device (not a kitchen spoon).

Remove an **orally disintegrating tablet** from the package with dry hands only when you are ready to use the medicine. Allow the **orally disintegrating tablet** to dissolve in your mouth without chewing.

Your dose needs may change if you switch to a different brand, strength, or form of this medicine. **Avoid medication** errors by using only the medicine your doctor prescribes.

Your doctor will need to check your progress on a regular basis and may need medical tests to check your heart function. **Tell any doctor who treats you that you are using this medicine.**

Store this medicine in the original container at room temperature away from moisture and heat.

Do not keep leftover medicine. **Ask your pharmacist about a drug take-back program**. You may also mix the leftover medicine with cat litter or coffee grounds in a sealed plastic bag and throw the bag in the trash.

Detailed Adzenys XR-ODT dosage information

What happens if I miss a dose?

Take the missed dose as soon as you remember, but not late in the day. Skip the missed dose if it is almost evening. **Do not** take two doses at one time.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222. An overdose can be fatal.

Overdose symptoms may include restlessness, tremor, muscle twitches, rapid breathing, confusion, hostility, hallucinations, heart problems, blood pressure changes, panic, muscle pain or weakness, stomach cramps, vomiting, or diarrhea. These symptoms may be followed by depression and tiredness. Overdose may also lead to seizure or coma.

What should I avoid while taking Adzenys XR-ODT?

Avoid drinking fruit juices such as cranberry juice or taking vitamin C at the same time you take Adzenys XR-ODT. These can make your body absorb less of Adzenys XR-ODT.

Avoid drinking alcohol.

Avoid driving or hazardous activity until you know how this medicine will affect you. Your reactions could be impaired.

What other drugs will affect Adzenys XR-ODT?

Sometimes it is not safe to use certain medicines at the same time. Some drugs can affect your blood levels of other drugs you use, which may increase side effects or make the medicines less effective.

Ask your doctor before using a stomach acid medicine (including Alka-Seltzer or sodium bicarbonate). Some of these medicines can change the way your body absorbs Adzenys XR-ODT and may increase side effects.

Tell your doctor about all your current medicines. Many drugs can affect Adzenys XR-ODT, especially:

- antidepressant including desipramine, protriptyline, paroxetine, fluoxetine;
- lithium or other medicine to treat depression or mental illness;
- blood pressure medicine;
- a blood thinner (warfarin, Coumadin, Jantoven);
- · cold or allergy medicine that contains a decongestant;
- · opioid (narcotic) medicine; or
- · seizure medicine.

This list is not complete and many other drugs may affect Adzenys XR-ODT. This includes prescription and over-

the-counter medicines, vitamins, and herbal products. Not all possible drug interactions are listed here.

Adzenys XR-ODT drug interactions (more detail)

Does Adzenys XR-ODT interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

Adzenys XR-ODT	
+	
Enter a drug name	Add

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Other brands

Dyanavel XR, Evekeo, Adzenys ER, Evekeo ODT

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Further information

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation

ം Risk data available

CSA Schedule*

2 High potential for abuse

Approval History

Drug history at FDA

User Reviews & Ratings

6.3 / 10

63 Reviews

Images

Adzenys XR-ODT 3.1 mg (A1)



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