

Adzenys XR-ODT

(amphetamine extended-release orally disintegrating tablet)

Full Prescribing Information	DailyMed Drug Information
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Forms/Strengths

- **Orally Disintegrating Tablets:** 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg, 18.8 mg

Dosing

- **Age:** ≥ 6 y/o
- **Onset:** ~ 30 min
- **Duration:** ~12 hours
- **Release Profile:** 50% IR, 50% ER
- **Considerations:** Orange-flavored. May be taken with or without food. **Allow tablet to disintegrate in saliva before swallowing.**
 - [Adderall XR Equivalent Doses](#)
- **Initial Dose:**
 - 6-17 y/o: 6.3 mg
 - 18+ y/o: 12.5 mg
- **Titration:** 3.1 mg - 6.3 mg weekly
- **Max Dose:**
 - 6-12 y/o: 18.8 mg/day
 - 13+ y/o: 12.5 mg/day

Equivalent Doses of ADZENYS XR-ODT and ADDERALL XR						
ADZENYS XR-ODT	3.1 mg	6.3 mg	9.4 mg	12.5 mg	15.7 mg	18.8 mg

ADDERALL XR	5 mg	10 mg	15 mg	20 mg	25 mg	30 mg
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Important Note: To avoid substitution errors and overdose, **do not substitute** for other amphetamine products on a milligram-per-milligram basis due to different amphetamine base compositions and pharmacokinetic profiles.

Quick Facts

- Increases synaptic norepinephrine/dopamine via enhanced presynaptic release and reuptake inhibition
- Improves focus, attention, impulse control
- Common side effects: decreased appetite, insomnia, elevated blood pressure
- Extended-release ODT with dual-phase (immediate and delayed) release for rapid onset and sustained effect
- Unique ODT formulation that disintegrates on the tongue without water

Indications

- **Attention Deficit Hyperactivity Disorder (ADHD) (ICD-10: F90.0)**

Off-Label Uses

- **Narcolepsy (ICD-10: G47.411):** Occasionally used off-label, though not FDA-approved for this indication.

How to Take

- Take **once daily in the morning** to reduce the risk of insomnia.
- **Do not crush, chew, or split** the tablet.
- Place the **orally disintegrating tablet (ODT) on the tongue** and allow it to dissolve completely; do not swallow whole.
- Can be taken **with or without food**.

Side Effects

- **Common:**
 - Insomnia, irritability, anxiety
 - Decreased appetite, weight loss
 - Dry mouth, nausea, abdominal pain
 - Increased blood pressure, heart rate
 - **Serious:**
 - Rare cardiovascular events (arrhythmias, sudden death in at-risk populations)
 - Psychiatric effects: mania, aggression, or psychosis
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Monitoring / Labs

- **Cardiovascular:** Baseline and routine monitoring of **heart rate and blood pressure**.
 - **Growth in Pediatrics:** Regular monitoring of **height and weight** to detect growth suppression.
 - **Psychiatric Symptoms:** Observe for **mood changes, anxiety, or psychosis**.
 - **Abuse Potential:** Monitor for **misuse or diversion**.
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Education

- **When to Call the Doctor**
 - **Severe mood changes, aggression, or suicidal thoughts.**
 - **Chest pain, rapid heartbeat, or shortness of breath.**
 - **Uncontrolled movements, tics, or worsening anxiety.**
 - **Numbness, coldness, or color changes in fingers or toes.**
 - **Signs of serotonin syndrome, such as agitation, rapid heartbeat, or tremors.**
- **Safety Tips:**
 - **Monitor blood pressure and heart rate** regularly, especially in patients with cardiovascular risk.
 - **Use caution in patients with anxiety, bipolar disorder, or psychosis**, as symptoms may worsen.
 - **Avoid caffeine and other stimulants**, which may amplify side effects.
 - **Ensure adequate hydration and nutrition**, as appetite suppression is common.
 - **Tapering may be required** if discontinuing after long-term use.
- **Tips for Pediatric Patients:**
 - **Encourage a balanced diet** to counteract appetite suppression.
 - **Monitor school performance and behavioral changes.**
 - **Administer in the morning before school** for optimal effect.

- **Observe for sleep disturbances and adjust timing if necessary.**
 - **Communicate with teachers and caregivers** about medication effects.
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Additional Information

- **Contraindications:**
 - **Hypersensitivity** to amphetamines or formulation components.
 - **Use within 14 days of MAOI therapy** (risk of hypertensive crisis).
 - Symptomatic **cardiovascular disease, moderate-to-severe hypertension, hyperthyroidism, glaucoma.**
 - **History of substance use disorder**, unless benefits outweigh risks.
 - **Pregnancy:**
 - **Category C**; use only if benefits outweigh risks.
 - May cause **neonatal withdrawal symptoms** or **low birth weight**.
 - **Lactation:**
 - **Excreted in breast milk; not recommended** due to potential infant exposure.
 - **Drug Interactions:**
 - **Serotonergic drugs** (e.g., SSRIs, SNRIs, MAOIs) increase **serotonin syndrome risk**.
 - **Acidifying agents** (e.g., ascorbic acid) may reduce drug absorption.
 - **Alkalinizing agents** (e.g., sodium bicarbonate) may increase amphetamine levels.
 - May potentiate **hypertensive effects** of certain medications (e.g., decongestants, beta-agonists).
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