

Adzenys XR-ODT

(amphetamine extended-release orally disintegrating tablet)

[Full Prescribing Information](#)

[DailyMed Drug Information](#)

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
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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

- **Mixed amphetamine salts** (75% dextroamphetamine base, 25% levoamphetamine base); increases synaptic **norepinephrine and dopamine** via enhanced release and reuptake inhibition
- Dual-release profile (**50% immediate, 50% extended**) for rapid onset and all-day coverage in ADHD
- **Improves core ADHD symptoms:** inattention, hyperactivity, impulsivity
- **Black box warning:** High potential for **abuse, misuse, addiction**, overdose, and death; Schedule II controlled substance
- Unique **ODT formulation** dissolves on tongue without water; orange flavor improves palatability
- Common effects: **appetite suppression, insomnia, ↑BP/HR**; monitor growth in children
- **Not interchangeable** with other amphetamines on mg basis due to base equivalence differences

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**.
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Side Effects

- **Common:**
 - **CNS:** insomnia, headache, anxiety, irritability, dizziness
 - **GI:** decreased appetite, weight loss, dry mouth, nausea, abdominal pain
 - **CV:** ↑ heart rate, ↑ blood pressure
 - **Other:** asthenia (fatigue)
 - **Serious:**
 - **Black box: Abuse/misuse/addiction** leading to overdose/death
 - **CV:** sudden death, myocardial infarction, stroke, arrhythmias (esp. with structural heart defects)
 - **Psych:** new/exacerbated psychosis, mania, aggression, hallucinations
 - **Peripheral vasculopathy:** Raynaud's-like symptoms (pain, numbness, color change in fingers/toes)
 - **Serotonin syndrome** (with serotonergics): hyperthermia, rigidity, seizures
 - **Growth suppression** in children
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Monitoring / Labs

- **Baseline/periodic:** BP, HR, weight, height (pediatrics), BMI
 - Assess growth every 3-6 months in children; plot on charts
 - Monitor for **psychiatric changes**, tics, substance misuse
 - **LFTs, CBC** if long-term or symptoms (e.g., dark urine)
 - ECG if cardiac history
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Education

- **When to Call the Doctor:**
 - Chest pain, palpitations, shortness of breath, fainting
 - Severe anxiety, hallucinations, mood changes, suicidal thoughts
 - Finger/toe pain, numbness, color changes (cold/pale/blue)
 - Prolonged erection (>4 hours), uncontrolled tics/movements
 - Signs of overdose: agitation, hallucinations, hyperthermia, seizures
- **Safety Tips:**
 - Take only as prescribed; **store securely** (controlled substance)

- Avoid alcohol, caffeine, OTC decongestants (↑CV effects)
 - Report all meds/supplements to avoid interactions
 - No driving/operating machinery until effects known
 - **Tapering may be required** if discontinuing after long-term use.
 - **Parent Tips for Pediatric Patients:**
 - Give **before school** to minimize sleep interference
 - Use pill organizer or reminders; track appetite/weight weekly
 - Partner with school (teacher reports on focus/behavior)
 - Promote healthy meals/snacks despite appetite loss
 - Watch for **growth delays**; annual pediatrician review
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Additional Information

- **Contraindications:**
 - Known hypersensitivity to amphetamines
 - **MAOI use within 14 days** (hypertensive crisis)
 - Advanced arteriosclerosis, symptomatic heart disease, moderate-severe HTN, hyperthyroidism, glaucoma
 - History of drug abuse
 - **Pregnancy: Category C**; potential fetal harm (↓birth weight, withdrawal); use only if benefit > risk (APLENZIN registry)
 - **Lactation:** Excreted in milk; **avoid** or discontinue nursing
 - **Drug Interactions:**
 - **CYP2D6 inhibitors** (e.g., bupropion, fluoxetine): ↑ amphetamine levels
 - **MAOIs/serotonergics:** serotonin syndrome, hypertensive crisis
 - **Acidifiers** (vit C): ↓ absorption; **alkalinizers** (NaHCO₃): ↑ levels
 - **Pressors** (decongestants): additive HTN/tachycardia
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References

1. Amphetamine XR-ODT Prescribing Information, Aytu BioPharma, 2023, <https://www.fffenterprises.com/assets/downloads/product-information/aytu-biopharma/pi-AMPHETAMINE-XR-ODT.pdf>
2. DailyMed: Amphetamine extended-release orally disintegrating tablets, 2023, <https://dailymed.nlm.nih.gov/dailymed/medguide.cfm?setid=48d0f55c-f847-4d26-b2ed-94b5a2770228>

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