Adderall XR

(dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine sulfate, amphetamine aspartate)

Adderall XR (mixed amphetamine salts, extended-release); CII

Full Prescribing Information	DailyMed Drug Information

Summary

Adderall XR is a once-daily extended-release amphetamine capsule approved for ADHD from age 6, using immediate- and delayed-release beads to reproduce immediate-release Adderall taken twice, four hours apart. It is a fixed 3:1 ratio of dextroamphetamine to levoamphetamine salts, and unlike methylphenidate it both blocks reuptake and drives catecholamine release. Its differentiator against Mydayis is the age floor: this is the mixed-salts option for a school-age child, where Mydayis starts at 13. Schedule II; brand and generic.

Forms & Strengths

- **Extended-release capsules:** 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg

Dosing

- **Age:** ≥ 6 y/o; not recommended below 6 years
- **Onset:** 30-60 min, from the immediate-release bead fraction
- **Duration:** 10-12 hours

- **Release Profile:** Biphasic; immediate-release plus delayed-release beads in one capsule, Tmax about 7 hours
- **Initial Dose:**
  - 6-12 y/o: 10 mg once daily in the morning; 5 mg where a lower start is judged appropriate
  - 13-17 y/o: 10 mg once daily in the morning
  - ≥ 18 y/o: 20 mg once daily in the morning
  - Severe renal impairment (GFR 15 to < 30): 5 mg, 6-17 y/o; 15 mg, adults. ESRD not recommended
- **Titration:**
  - 6-12 y/o: increase by 5 mg or 10 mg at weekly intervals
  - 13-17 y/o: a single increase to 20 mg after one week if control is inadequate
- **Max Dose:**
  - 6-12 y/o: 30 mg/day; doses above 30 mg/day have not been studied in children. Severe renal impairment: 20 mg/day
  - 13-17 y/o: no numeric maximum in the label; no added benefit above 20 mg/day in the adolescent trial
  - ≥ 18 y/o: no numeric maximum; same finding above 20 mg/day
- **Considerations:** Give on awakening and avoid afternoon doses; a capsule may not be divided, and the patient must not take less than one whole capsule per day.

Pharmacology

- **Mechanism:** Blocks reuptake at DAT and NET and promotes presynaptic catecholamine release via VMAT2 and TAAR1; the release component is what distinguishes amphetamines from methylphenidate
- **Delivery / Release:** Immediate-release plus delayed-release beads, giving a profile comparable to IR Adderall taken twice, 4 hours apart; Tmax about 7 hours
- **Formulation:** Fixed 3:1 dextro- to levoamphetamine; the levo isomer carries more peripheral and noradrenergic effect
- **Metabolism:** CYP2D6 to 4-hydroxyamphetamine. d-amphetamine half-life 9-11 h, l-amphetamine 11-14 h across pediatric ages. Renal excretion is pH dependent
- **Pharmacogenomics:** No genotype-directed dosing in the label; the actionable consequence is the CYP2D6-inhibitor interaction
- **Class Positioning:** One dose instead of two versus Adderall. Mydayis runs to about 16 hours but starts at 13; this is the mixed-salts ER option below that age

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Indications

- **ADHD** (ICD-10: F90.0, F90.1, F90.2, F90.8, F90.9): patients ≥ 6 y/o. The only approved indication.

Off-Label Uses

- **Narcolepsy** (ICD-10: G47.419): off-label at every age; insufficient. Use an approved product: Adderall, Zenzedi, Dexedrine Spansule.
- **ADHD under 6 years** (ICD-10: F90.x): insufficient. AAP names behavioral intervention first-line, and methylphenidate if medication is added (AAP 2019).
- **Where the evidence does not support use:** depression augmentation and post-TBI attention; no pediatric evidence for ER mixed salts (AHRQ 2024).
- **Cognitive enhancement without ADHD:** not an indication; not supported.

Contraindications & Warnings

- **Boxed Warning:** Abuse, misuse, and addiction; risk of overdose and death, rising with higher doses and non-oral routes. Assess abuse risk before prescribing and monitor throughout.
- **Contraindicated:**
  - Known hypersensitivity or idiosyncrasy to amphetamine or any component
  - MAOI use, current or within 14 days
- **Use with caution** (label Warnings, not contraindications):
  - Structural cardiac abnormality, cardiomyopathy or serious arrhythmia; the label says avoid
  - Hypertension; expect mean rises of 2-4 mmHg and 3-6 bpm
  - Psychosis or bipolar disorder; new psychotic or manic symptoms in about 0.1%
  - Prior seizure or EEG abnormality
  - Peripheral vasculopathy including Raynaud phenomenon
  - Tics or Tourette syndrome, personal or family
  - Substance use disorder, patient or household
  - Severe renal impairment; ESRD not recommended
- **Screen before starting:**
  - Cardiac and family history of sudden death; ECG only if positive
  - Tics, Tourette syndrome and mania risk factors, including family history
  - Abuse and diversion risk
  - Baseline height, weight, blood pressure and heart rate
  - Renal function where impairment is suspected

Drug Interactions

- **MAOIs** (phenelzine, tranylcypromine, selegiline, linezolid, IV methylene blue): hypertensive crisis; do not give within 14 days.

- **Serotonergic agents** (SSRIs, SNRIs, TCAs, triptans, fentanyl, lithium, tramadol, buspirone, St John's Wort): serotonin syndrome; counsel on symptoms and stop both if it occurs.
- **CYP2D6 inhibitors** (fluoxetine, paroxetine, bupropion, quinidine): raise exposure; start lower.
- **Alkalinizing agents** (sodium bicarbonate, acetazolamide): raise levels; the label says avoid.
- **Acidifying agents** (ascorbic acid, fruit juices): lower levels; adjust on response, not assumed failure.
- **Tricyclics** (desipramine, protriptyline): sustained rise in brain d-amphetamine with potentiated cardiovascular effect; monitor and adjust.
- **Proton pump inhibitors** (omeprazole): shorten Tmax, so the dose lands and fades earlier; adjust timing.

Administration

- Once daily on awakening; afternoon doses cost sleep.
- With or without food; a high-fat meal delays Tmax only.
- Swallow whole, or sprinkle the entire contents on applesauce, eaten immediately without chewing. Do not store.
- Do not divide a capsule; sprinkling is a swallowing accommodation, not a dose split.
- Where neither route works, Adzenys XR-ODT has a published conversion from this product.
- Switching from IR Adderall: same total daily dose once daily, then titrate weekly. The only conversion the label supports.
- Do not substitute milligram-for-milligram for Mydayis or any other amphetamine.
- If a dose is missed, skip it; do not double up.

Side Effects

- **Common, 6 to 12:** loss of appetite 22%, insomnia 17%, abdominal pain 14%, emotional lability 9%, vomiting 7%, nervousness 6%, weight loss 4%
- **Common, 13 to 17:** loss of appetite, insomnia, abdominal pain, weight loss, nervousness each ≥ 5%
- **Serious:**
  - Sudden death with structural cardiac disease. Investigate exertional chest pain or syncope immediately.
  - Psychosis, mania and new aggression. Consider discontinuing.
  - Serotonin syndrome. Stop both drugs and treat supportively.
  - Seizures. Discontinue.
  - Peripheral vasculopathy with digital ulceration. Reduce or stop; refer if persistent.

    - Growth suppression; mean 4-week weight change -1.1 lbs at 10 mg, -2.8 lbs at 20 mg. Interrupt if growth falls behind.
    - New or worsening motor and verbal tics. Discontinue if clinically appropriate.

Monitoring & Labs

- **Cardiovascular:** heart rate and blood pressure at baseline, each dose change, and every 6 months; act above the age-specific 95th percentile.
- **Growth:** height, weight and BMI charted at baseline and every 6 months; interrupt if the child crosses two major percentile lines.
- **Appetite and Sleep:** at every visit and every dose change.
- **Psychiatric and tics:** psychosis, mania, aggression, emotional lability and new tics at every visit.
- **Peripheral vasculopathy:** inspect fingers and toes at every visit.
- **Abuse and Diversion:** adherence, pill counts and PDMP check at every refill.
- **Renal function:** at baseline where impairment is suspected, and annually.
- **Laboratory:** none routinely; amphetamines interfere with urinary steroid assays.

Discontinuation & Taper

- May be stopped abruptly at therapeutic doses; no taper is required.
- Withdrawal after abrupt stop following prolonged use: dysphoria, fatigue, vivid dreams, increased appetite.
- Late-afternoon rebound irritability and hunger is offset, not withdrawal.
- Interrupt treatment where growth falls behind; the label names interruption, not dose reduction.
- Drug holidays are reasonable where appetite or growth suppression is limiting.

Pregnancy & Lactation

- **Pregnancy:** No drug-associated risk of major birth defects or miscarriage. Premature delivery and low birth weight reported. Monitor exposed newborns for withdrawal.
- **Lactation:** Label says breastfeeding is not recommended. Relative infant dose 2 to 13.8%, milk/plasma ratio 1.9 to 7.5; no reported infant adverse effects.
- **Milk supply:** Dose-related prolactin suppression up to 40% may impair production before lactation is established. (LactMed 2025)
- **Exposure Registry:** National Pregnancy Registry for Psychostimulants, 1-866-961-2388.

Counseling Points

- **Counsel the family on:**
  - Sprinkling is a swallowing accommodation, not a dose split; use a lower strength instead.
  - The applesauce must be eaten immediately and completely.
  - The 10 to 12 hour window; ask what time the fade starts before changing the dose.
  - For adolescents, no added benefit above 20 mg/day in the label's own trial.
  - Vitamin C and fruit juice can mimic treatment failure; bicarbonate and antacids raise levels.
  - Move the largest meal to breakfast and to the evening.
  - Locked storage; sharing or selling a Schedule II medication is a felony.
  - Bring a teacher rating scale to the next visit.
- **Advise them to call for:**
  - Chest pain on exertion, fainting, or a racing heart that does not settle.
  - New hallucinations, or new suspicious or fearful thinking.
  - Numbness, coldness or colour change in the fingers or toes.
  - A new or markedly worse tic, or a seizure of any kind.
  - Weight loss, or clothes fitting more loosely over a few weeks.
  - Agitation, shivering, sweating or confusion after an antidepressant change.

References

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