Adderall

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

Adderall (mixed amphetamine salts); CII

Full Prescribing Information	DailyMed Drug Information

Summary

Adderall is an immediate-release, short-acting amphetamine tablet approved for ADHD from age 3 and for narcolepsy from age 6. It is a fixed 3:1 ratio of dextroamphetamine to levoamphetamine salts, and unlike methylphenidate it both blocks reuptake and drives presynaptic catecholamine release. Its short duration makes it useful for afternoon coverage or for patients who cannot tolerate a full-day agent, at the cost of multiple daily dosing. Schedule II; brand and generic.

Forms & Strengths

- **Tablets:** 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 20 mg, 30 mg

Dosing

- **Age:**
  - ADHD: ≥ 3 y/o
  - Narcolepsy: ≥ 6 y/o
- **Onset:** 30-60 min

- **Duration:** 4-6 hours
- **Initial Dose:**
  - 3-5 y/o: 2.5 mg daily
  - ≥ 6 y/o: 5 mg once or twice daily
- **Titration:**
  - 3-5 y/o: increase by 2.5 mg at weekly intervals
  - ≥ 6 y/o: increase by 5 mg at weekly intervals
- **Max Dose:**
  - ADHD: 40 mg/day; the label states only in rare cases will it be necessary to exceed this
  - Narcolepsy: usual range 5-60 mg/day
- **Considerations:** Give the first dose on waking, with further doses at 4-6 hour intervals. May be taken with or without food; a high-fat meal may delay absorption. Avoid late-afternoon dosing.

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
- **Formulation:** Fixed 3:1 ratio of dextroamphetamine to levoamphetamine salts; the levo isomer contributes more peripheral and noradrenergic effect
- **Class Positioning:** Covers a discrete window rather than a school day; ER siblings of the same salts are Adderall XR and Mydayis
- **Elimination:** Urinary excretion is pH dependent, which is why acidifying and alkalinizing agents change exposure

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Indications

- **ADHD** (ICD-10: F90.0, F90.1, F90.2, F90.8, F90.9): patients ≥ 3 y/o
- **Narcolepsy** (ICD-10: G47.419): patients ≥ 6 y/o

Off-Label Uses

- **Attention problems after TBI** (ICD-10: S06.x): limited data, and largely for methylphenidate; insufficient for amphetamine in youth.
- **Depression augmentation** (ICD-10: F32.x, F31.x): adult literature only; insufficient in children.
- **Cognitive enhancement without ADHD:** not an indication; not supported.

Contraindications & Warnings

- **Boxed Warning:** Abuse, misuse, and addiction; risk of overdose and death. Assess abuse risk before prescribing and monitor throughout. Educate the family on secure storage and disposal of unused drug.
- **Contraindicated:**
  - Known hypersensitivity to amphetamine or any component of the product.
  - Current use of an MAOI, or use within the preceding 14 days, because of hypertensive crisis.
- **Use with caution** (Warnings in this label, not contraindications):
  - Known structural cardiac abnormality, cardiomyopathy, or serious arrhythmia, because of sudden death reports.
  - Pre-existing hypertension, because blood pressure and heart rate rise.
  - Pre-existing psychosis or bipolar disorder, because of exacerbation and treatment-emergent mania.
  - History of substance use disorder in the patient or household.
  - Peripheral vasculopathy including Raynaud phenomenon.
- **Screen before starting:**
  - Cardiac history, exertional syncope, family history of sudden cardiac death before 50. ECG only if positive.
  - Personal or family history of bipolar disorder, psychosis, and tics.
  - Abuse and diversion risk, which the boxed warning requires.
  - Baseline height, weight, blood pressure, and heart rate.

Drug Interactions

- **MAOIs:** contraindicated within 14 days; risk of hypertensive crisis.
- **Serotonergic agents** (SSRIs, SNRIs, TCAs, triptans, lithium, fentanyl, tramadol, buspirone, St John's Wort, tryptophan): serotonin syndrome; counsel on symptoms and reassess when adding.
- **Alkalinizing agents** (sodium bicarbonate, some antacids): raise amphetamine blood levels and potentiate its effect.
- **Acidifying agents** (ascorbic acid, fruit juices): lower amphetamine blood levels and reduce efficacy.
- **Sympathomimetics** (decongestants, beta-agonists): additive cardiovascular effect.

Administration

- Give the first dose on waking; give any further doses at 4-6 hour intervals.

- May be taken with or without food. A high-fat meal may delay absorption.
- Avoid late-afternoon and evening doses, which cause insomnia.
- If a dose is missed, skip it rather than giving it late in the day; do not double up.
- A capsule of mixed amphetamine salts is not this product; confirm IR versus ER before substituting.
- Store securely. This is a Schedule II product and household diversion is a real risk.

Side Effects

- **Common:** decreased appetite, insomnia, weight loss, headache, dry mouth, irritability, anxiety, abdominal pain, increased heart rate and blood pressure
- **Serious:**
  - Sudden death, myocardial infarction and stroke, reported in patients with structural cardiac abnormalities or other serious cardiac problems.
  - Psychosis, mania, and new aggression, including in patients with no prior psychiatric history.
  - Serotonin syndrome when combined with serotonergic agents.
  - Peripheral vasculopathy including Raynaud phenomenon: reassess at each visit; discontinue if digital ulceration occurs.
  - Growth suppression in children.
  - Priapism, which may require surgical intervention and can occur after dose reduction or withdrawal.

Monitoring & Labs

- **Cardiovascular:** heart rate and blood pressure at baseline, at each dose change, and every 6 months.
- **Growth:** height, weight and BMI plotted on a growth chart at baseline and every 6 months; evaluate if a child crosses two major percentile lines.
- **Appetite and Sleep:** at every visit. These are the two most common reasons for discontinuation.
- **Psychiatric:** screen for new psychosis, mania, aggression and worsening tics at each visit.
- **Abuse and Diversion:** adherence, pill counts, PDMP check at each refill. Uncontrolled alternatives: Strattera, Qelbree.
- **Laboratory:** no routine laboratory monitoring is required.

Discontinuation & Taper

- Immediate-release amphetamine can be stopped abruptly at therapeutic doses; no taper is required.
- Expect rebound irritability, hunger and fatigue at offset; this is pharmacodynamic, not withdrawal.
- Drug holidays are reasonable where appetite or growth suppression is the limiting problem.

Pregnancy & Lactation

- **Pregnancy:** Use only if benefit justifies fetal risk. No exposure registry in this label.
- **Lactation:** Label advises against nursing. LactMed: milk levels ~1.9-2.1% of maternal dose; therapeutic doses considered compatible if the infant is watched for irritability, insomnia and poor feeding. (LactMed 2025)
- **Milk supply:** Dose-related prolactin suppression of ~25-40%; large doses may impair milk production before lactation is established. (LactMed 2025)

Counseling Points

- **Counsel the family on:**
  - The 4-6 hour window; the afternoon drop-off is the drug wearing off, not failing.
  - Rebound irritability and hunger at offset; not a reason to increase the dose.
  - Appetite suppression peaking midday; move the largest meal to breakfast and to the evening.
  - No doses after roughly 4 pm; later dosing costs sleep.
  - Secure storage; sharing or selling a Schedule II medication is a felony.
  - Bringing a teacher rating scale to the next visit rather than a verbal impression.
- **Advise them to call for:**
  - Chest pain, 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.
  - Weight loss, or clothes fitting more loosely over a few weeks.
  - A painful erection lasting more than a few hours, which is a surgical emergency.

References

1. DailyMed. Adderall (dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate) tablets prescribing information. Teva Pharmaceuticals USA. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f22635fe-821d-4cde-aa12-

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2. LactMed. Amphetamine. Drugs and Lactation Database, National Institute of Child Health and Human Development. 2025. https://www.ncbi.nlm.nih.gov/books/NBK501307/

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