Evekeo

(amphetamine sulfate)

Evekeo (amphetamine sulfate); CII

Full Prescribing Information	DailyMed Drug Information

Summary

Evekeo is an immediate-release, short-acting tablet of racemic amphetamine sulfate, approved for ADHD from age 3, narcolepsy from age 6, and short-term use in exogenous obesity from age 12. Unlike Adderall it is a single-entity salt rather than a mixed-salt blend, and unlike Zenzedi it carries the l-isomer too; that racemic composition is why you would reach for it. Schedule II; brand and generic.

Forms & Strengths

- **Tablets** (5 mg single-scored, 10 mg double-scored): 5 mg, 10 mg

Dosing

- **Age:**
  - ADHD: ≥ 3 y/o
  - Narcolepsy: ≥ 6 y/o
  - Exogenous obesity: ≥ 12 y/o
- **Onset:** 30 to 60 min
- **Duration:** 4 to 6 hours
- **Initial Dose:**
  - ADHD, 3-5 y/o: 2.5 mg daily
  - ADHD, ≥ 6 y/o: 5 mg once or twice daily
  - Narcolepsy, 6-11 y/o: 5 mg daily
  - Narcolepsy, ≥ 12 y/o: 10 mg daily

    - Exogenous obesity, ≥ 12 y/o: 5-10 mg per dose, 30-60 min before meals
- **Titration:**
    - ADHD, 3-5 y/o: 2.5 mg every 7 days
    - ADHD, ≥ 6 y/o: 5 mg every 7 days
    - Narcolepsy, 6-11 y/o: 5 mg every 7 days
    - Narcolepsy, ≥ 12 y/o: 10 mg every 7 days
- **Max Dose:**
    - ADHD: 40 mg/day, at any age
    - Narcolepsy: usual range 5-60 mg/day in divided doses
    - Exogenous obesity: up to 30 mg/day in divided doses of 5-10 mg
- **Considerations:** First dose on awakening, then one or two further doses at 4-6 hour intervals; the maximum is set by indication, not by weight, and late evening doses cause insomnia.

Pharmacology

- **Mechanism:** Blocks reuptake at DAT and NET and promotes presynaptic catecholamine release via VMAT2 and TAAR1; the release component distinguishes amphetamines from methylphenidate
- **Delivery / Release:** Plain immediate-release tablet; single early peak, one block of coverage per dose
- **Formulation:** Racemic amphetamine sulfate, equal d- and l-isomer. Per the label the l-isomer is more potent in cardiovascular activity and much less potent in CNS excitatory effects
- **Metabolism:** CYP2D6 forms active 4-hydroxyamphetamine; urinary excretion is pH dependent; this label publishes no half-life
- **Class Positioning:** A single salt, not the 3:1 d:l blend of Adderall, so relatively more peripheral effect per unit of CNS effect; unlike pure-dextroamphetamine Zenzedi and ProCentra it adds the l-isomer back
- **Interchange:** not milligram-for-milligram equivalent to any other amphetamine moiety

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Indications

- **ADHD** (ICD-10: F90.0, F90.1, F90.2, F90.8, F90.9): patients ≥ 3 y/o, within a total treatment program
- **Narcolepsy** (ICD-10: G47.419): patients ≥ 6 y/o
- **Exogenous obesity** (ICD-10: E66.9): patients ≥ 12 y/o, short-term adjunct of a few weeks, second-line only; the label puts the gain over placebo at a fraction of a pound per week

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Off-Label Uses

- **None established** for this moiety outside its labelled indications.
- **Where the evidence does not support use:**
  - **Non-ADHD indications in youth:** AHRQ CER 267 graded none; insufficient (AHRQ 2024).
  - **Weight management under 12, first-line, or beyond a few weeks:** not supported.
  - **Cognitive enhancement without ADHD:** not supported.

Contraindications & Warnings

- **Boxed Warning:** Abuse, misuse, and addiction. High potential for abuse, leading to substance use disorder; overdose and death, more so at higher doses or by snorting or injection. Assess risk before prescribing; reassess throughout.
- **Contraindicated:**
  - Known hypersensitivity to amphetamine products
  - MAOI use, current or within 14 days; hypertensive crisis
- **Use with caution** (Warnings in this label, not contraindications):
  - Structural cardiac abnormality, cardiomyopathy, serious arrhythmia or coronary disease; label says avoid, for sudden death
  - Hypertension, including mild, which the label names explicitly
  - Pre-existing psychosis; bipolar disorder, for treatment-emergent mania
  - Prior seizure or prior EEG abnormality; this label carries an explicit Seizures warning and directs discontinuation if a seizure occurs
  - Motor or verbal tics, or Tourette syndrome
  - Peripheral vasculopathy including Raynaud phenomenon
  - Substance use disorder in the patient or the household
- **Screen before starting:**
  - Cardiac history, family history of sudden death or arrhythmia, and exam
  - Personal and family history of tics or Tourette syndrome
  - Mania risk: personal or family depression, bipolar disorder, suicide
  - Abuse and diversion risk; baseline height, weight, BP and HR

Drug Interactions

- **MAOIs** (also linezolid, IV methylene blue): hypertensive crisis, malignant hyperpyrexia, sometimes fatal. Do not co-prescribe; confirm a 14 day washout.
- **Serotonergic agents** (SSRIs, SNRIs, TCAs, triptans, lithium, fentanyl, tramadol, buspirone, St John's Wort): serotonin syndrome. Start lower; stop both drugs if symptoms

appear.

- **CYP2D6 inhibitors** (paroxetine, fluoxetine, quinidine, ritonavir): raise exposure and serotonin syndrome risk. Prefer an alternative; else start lower.
- **Urinary pH agents:** acidifiers (ascorbic acid, fruit juice, ammonium chloride, methenamine) lower levels and efficacy; alkalinizers (bicarbonate, antacids, acetazolamide, thiazides) raise them. Check both before changing the dose.
- **Tricyclic antidepressants** (desipramine, protriptyline): sustained rise in brain d-amphetamine, potentiated cardiovascular effect. Monitor BP and HR; titrate slowly.
- **Sympathomimetics and antihypertensives:** additive cardiovascular effect; hypotensive effect antagonized. Avoid OTC decongestants; recheck blood pressure.

Administration

- First dose on awakening; one or two further doses at 4-6 hour intervals.
- Split the scored 5 mg tablet for the 2.5 mg preschool starting dose.
- Exogenous obesity only: dose 30 to 60 minutes before a meal; that timing does not apply to ADHD or narcolepsy.
- Avoid late evening doses; the label names resulting insomnia.
- No suspension, chewable or sprinkle form exists; any instruction to shake or open belongs to another product.
- Interrupt occasionally to see whether symptoms recur at a level requiring continued therapy; this is a label instruction.
- Store securely, preferably locked.

Side Effects

- **Common:** decreased appetite and weight loss, insomnia, overstimulation, irritability and dysphoria, headache, dizziness, dry mouth, unpleasant taste, bowel change, palpitations, tachycardia, elevated blood pressure.
- **Serious:**
  - Sudden death with structural cardiac abnormality or serious cardiac disease; avoid rather than monitor through it.
  - Psychosis or mania at recommended doses, roughly 0.1% in pooled stimulant trials; consider discontinuing.
  - Serotonin syndrome; stop both drugs and treat supportively.
  - Seizure; discontinue.
  - Peripheral vasculopathy including Raynaud phenomenon, rarely digital ulceration; reduce or stop, refer if persistent.
  - Growth suppression; interrupt in a child not growing or gaining as expected.
  - New or worsening tics and Tourette syndrome; discontinue if clinically appropriate.
  - Rhabdomyolysis, intestinal ischemia; priapism, a surgical emergency.

Monitoring & Labs

- **Cardiovascular:** HR and BP at baseline, each dose change, and every 6 months; mean rise 2-4 mm Hg and 3-6 bpm, investigate beyond that.
- **Growth:** height, weight and BMI charted at baseline and every 6 months; interrupt if crossing two major percentile lines.
- **Appetite and sleep:** every visit; usually fixed by timing rather than dose.
- **Psychiatric:** psychosis, mania, aggression, dysphoria at each visit and 2 weeks after any increase.
- **Tics and digits:** ask about tics and inspect fingers and toes for colour change, coolness or unexplained wounds at each visit.
- **Abuse and diversion:** adherence, pill counts and PDMP check at each refill; reassess need for therapy at least annually.
- **Laboratory:** none routinely; amphetamines interfere with urinary steroid determinations.

Discontinuation & Taper

- Can be stopped abruptly at therapeutic doses; no taper required.
- Physical dependence is labelled; withdrawal is dysphoria, depression, fatigue, vivid dreams, sleep change, increased appetite. Warn the family in advance.
- End-of-dose rebound irritability and hunger is pharmacodynamic offset, not withdrawal.
- Planned interruptions are asked for by this label; drug holidays suit appetite or growth as the limiting problem.

Pregnancy & Lactation

- **Pregnancy:** No adequate controlled studies. Embryotoxic and teratogenic in two mouse strains at about 41 times the maximum human dose; not in rabbits at 7 or rats at 12.5 times.
- **Pregnancy, clinical:** increased premature delivery and low birth weight in dependent mothers; infants may withdraw. Weigh rather than abstain.
- **Lactation:** the label says amphetamines enter milk and mothers should not nurse. LactMed: one narcolepsy case gave 1.9% to 2.1% of the maternal weight-adjusted dose. (LactMed 2025)
- **Lactation, practical:** some experts accept therapeutic doses, monitoring the infant for irritability, insomnia and feeding difficulty.
- **Lactation, milk supply:** prolactin suppressed 25% to 40% dose-dependently; large doses may impair milk production where lactation is not yet established. (LactMed 2025)

Counseling Points

- **Counsel the family on:**
  - The 4-6 hour window, and that a second or third dose usually covers the afternoon.
  - End-of-dose rebound irritability and hunger; not a signal to increase the dose.
  - Moving the last dose earlier rather than adding a sleep aid.
  - Appetite suppression peaking midday; largest meal at breakfast and in the evening.
  - Avoiding vitamin C loading and fruit juice around dosing, and asking before any antacid.
  - Secure, preferably locked storage; sharing a Schedule II medication is a felony.
  - Bringing a teacher rating scale to the next visit, and expecting a planned trial off medication.
- **Advise them to call for:**
  - Chest pain on exertion, fainting, or a racing heart that does not settle.
  - Any seizure, or a new staring spell.
  - New hallucinations, or new suspicious or fearful thinking.
  - Numbness, coldness or colour change in the fingers or toes, or an unexplained sore on a digit.
  - A new or markedly worse tic; new throat clearing or blinking.
  - Weight loss, or clothes fitting more loosely over a few weeks.
  - A painful erection lasting more than a few hours.

References

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