ProCentra

(dextroamphetamine sulfate)

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Full Prescribing Information	DailyMed Drug Information

Summary

ProCentra is an immediate-release, short-acting oral solution of single-entity dextroamphetamine sulfate, approved for ADHD from age 3 through 16 and for narcolepsy. It contains only the d-isomer and gives a short block of coverage per dose rather than a school day. Its differentiator is the liquid: the only immediate-release amphetamine titratable in fractions of a milligram for a preschooler or a child who cannot swallow. Schedule II; brand and generic.

Forms & Strengths

- **Oral solution** (bubblegum, colorless; 16 fl oz bottle): 5 mg/5 mL, that is 1 mg/mL

Dosing

- **Age:**
  - ADHD: 3-16 y/o, the range this label's indication is written for
  - Narcolepsy: ≥ 6 y/o, no upper bound
- **Onset:** 30 to 60 min
- **Duration:** 4 to 6 hours
- **Initial Dose:**
  - ADHD, 3-5 y/o: 2.5 mg daily, that is 2.5 mL
  - ADHD, 6-16 y/o: 5 mg once or twice daily
  - Narcolepsy, 6-11 y/o: 5 mg daily
  - Narcolepsy, ≥ 12 y/o: 10 mg daily
- **Titration:**

    - ADHD, 3-5 y/o: 2.5 mg every 7 days
    - ADHD, 6-16 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; the label says only in rare cases will it be necessary to exceed this
    - Narcolepsy: usual range 5-60 mg/day in divided doses
- **Considerations:** The maximum is set by indication, not by age or weight. First dose on awakening, then one or two more at 4-6 hour intervals. This is a solution, not a suspension; it does not need shaking.

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:** A true solution, already dissolved; no disintegration step, no modified-release component
- **Formulation:** d-isomer only; at the same milligram dose as a mixed-salt or racemic amphetamine, more CNS effect and less of the peripheral contribution the l-isomer carries
- **Metabolism:** 10 mg gave a mean peak of 33.2 ng/mL, half-life 11.75 hours, 38% urinary recovery over 48 hours; excretion is pH dependent
- **Half-life is not duration:** the dosing interval is 4 to 6 hours despite an 11.75 hour half-life
- **Class Positioning:** the moiety and release profile of Zenzedi in a form a 3 year old can take and that titrates continuously; Dexedrine Spansule is the extended-release sibling
- **Against Dyanavel XR,** the other liquid amphetamine: pure d-isomer, immediate-release, several doses daily

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Indications

- **ADHD** (ICD-10: F90.0, F90.1, F90.2, F90.8, F90.9): patients 3-16 y/o, within a total treatment program
- **Narcolepsy** (ICD-10: G47.419): patients ≥ 6 y/o; the label notes it seldom occurs under 12

Off-Label Uses

- **ADHD over age 16** (ICD-10: F90.x): outside this label's range, though the tablets carry an adult indication elsewhere. Use in a 17 year old who cannot swallow tablets is expert consensus.
- **Where the evidence does not support use:**
  - **Non-ADHD, non-narcolepsy indications in youth:** AHRQ CER 267 graded none (AHRQ 2024).
  - **Weight management:** unlike Evekeo, this label carries no obesity indication. Not supported.
  - **Cognitive enhancement without ADHD:** not supported.

Contraindications & Warnings

- **Boxed Warning:** Abuse, misuse, and addiction. High abuse potential 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, not contraindications):
  - Structural cardiac abnormality, cardiomyopathy, serious arrhythmia or coronary disease; label says avoid, for sudden death
  - Pre-existing hypertension; pre-existing psychosis; bipolar disorder, for treatment-emergent mania
  - Motor or phonic tics or Tourette syndrome; peripheral vasculopathy including Raynaud phenomenon
  - Substance use disorder in the household; a palatable liquid in a 16 ounce bottle is a different risk from a blister pack
- **Screen before starting:**
  - Cardiac history, family history of sudden death or arrhythmia, and exam
  - Personal and family history of tics; mania risk from personal or family depression, bipolar disorder or suicide
  - Abuse and diversion risk; baseline height, weight, BP, HR

Drug Interactions

- **MAOIs** (including furazolidone): hypertensive crisis, malignant hyperpyrexia, sometimes fatal. Confirm a 14 day washout.
- **Serotonergic agents** (SSRIs, SNRIs, TCAs, triptans, lithium, fentanyl, tramadol, buspirone): 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.

- **Acidifying agents** (ascorbic acid, fruit juices, ammonium chloride): lower absorption and efficacy. A caregiver mixing a dose into orange juice is creating this interaction; instruct that the dose is given straight.
- **Alkalinizing agents** (bicarbonate, antacids, acetazolamide): raise levels. Reduce the dose rather than assuming lost tolerance.
- **Tricyclic antidepressants** (desipramine, protriptyline): sustained rise in brain d-amphetamine. Monitor BP and HR; titrate slowly.
- **Sympathomimetics and antihypertensives:** additive cardiovascular effect; hypotensive effect antagonized. Avoid OTC decongestants; recheck BP.

Administration

- First dose on awakening, one or two more at 4-6 hour intervals, with or without food.
- **This is a solution, not a suspension. It does not need shaking.** Any instruction to shake the bottle was carried over from a different product.
- Measure with a calibrated oral syringe, never a spoon: at 1 mg/mL a 2.5 mg dose is 2.5 mL. Confirm the pharmacy supplied one; this label names no dosing device.
- **Give the dose straight, not in juice.** Fruit juice acidifies and lowers absorption, and is a common invisible cause of apparent treatment failure.
- Avoid late evening doses; the label names resulting insomnia.
- Interrupt occasionally to see whether symptoms recur at a level requiring continued therapy; a label instruction.
- Store at room temperature in a tight, light-resistant container, securely and preferably locked.

Side Effects

- **Common:** decreased appetite and weight loss, insomnia, overstimulation, irritability and dysphoria, headache, dizziness, tremor, 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.
  - Psychosis or mania, roughly 0.1% in pooled stimulant trials; consider discontinuing.
  - Serotonin syndrome; stop both drugs and treat supportively.
  - Peripheral vasculopathy including Raynaud phenomenon; reduce or stop.
  - Growth suppression; interrupt in a child not growing as expected.
  - New or worsening tics; rhabdomyolysis; intestinal ischemia.
  - Impotence and changes in libido, which an adolescent may not volunteer.

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.
- **Growth:** height, weight and BMI charted at baseline and every 6 months; this matters most in the 3 to 5 year olds the formulation exists to serve.
- **Appetite and sleep:** every visit; usually fixed by timing rather than dose.
- **Psychiatric, tics and digits:** psychosis, mania, aggression and dysphoria at each visit and 2 weeks after any increase; ask about motor and phonic tics and inspect the digits.
- **Dosing technique:** watch the caregiver draw a dose at first follow-up and whenever response turns erratic; ask whether it is being mixed into juice, which looks like tolerance.
- **Volume accounting:** at each refill reconcile volume dispensed against daily dose and days elapsed; a liquid cannot be pill-counted.
- **Abuse and diversion:** adherence and PDMP check at each refill; reassess need for therapy at least annually.
- **Laboratory:** none routinely; amphetamines interfere with urinary steroid assays.

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.
- 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, human data:** one VATER-association case report, bony deformity with tracheoesophageal fistula and anal atresia, after first-trimester use with lovastatin. One confounded case is not a causal finding.
- **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.
- **Lactation, dextroamphetamine:** four mothers on a mean 18 mg daily gave a median milk level of 219 mcg/L, 5.7% of the maternal dose, with all four infants normal. (LactMed 2025)

- **Lactation, milk supply:** a 20 mg dose suppressed prolactin about 40% postpartum; large doses may impair production where lactation is not established. (LactMed 2025)

Counseling Points

- **Counsel the family on:**
  - That this bottle does not need shaking, unlike ADHD liquids they may have used before. Say it explicitly.
  - Giving the dose straight rather than in orange juice, because acid turns a working dose into a failing one.
  - Measuring with the oral syringe, and that 1 mL equals 1 mg so a small volume error is a large dose error.
  - 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.
  - Appetite suppression peaking midday; largest meal at breakfast and in the evening.
  - Storing the bottle locked; bringing 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 or colour change in the fingers or toes.
  - A new or worse tic, new throat clearing or blinking; weight loss.
  - Any accidental swallow by another child; for a 16 ounce bottle of a Schedule II liquid that is an emergency call.

References

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