Dexedrine Spansule

(dextroamphetamine sulfate)

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Full Prescribing Information	DailyMed Drug Information

Summary

Dexedrine Spansule is a sustained-release dextroamphetamine capsule approved for narcolepsy and for ADHD in patients aged 6 to 16. It is single-isomer dextroamphetamine, so it carries no levoamphetamine and less peripheral noradrenergic load than Adderall XR at an equivalent dose. Its role is once-daily dextroamphetamine where the immediate-release tablet would need two or three doses; the label is candid that the pellet is only more convenient, not more effective. Schedule II; brand and generic.

Forms & Strengths

- **Sustained-release capsules (Spansule):** 5 mg, 10 mg, 15 mg

Dosing

- **Age:**
  - ADHD: 6-16 y/o, the label's own upper bound. Not recommended below 6 years
  - Narcolepsy: no age bound stated; the label gives a dose ladder from age 6
- **Onset:** 30-60 min, from the promptly released initial fraction
- **Duration:** 6 to 8 hours
- **Release Profile:** Sustained-release pellets; an initial dose released promptly, the remainder gradually. Tmax about 8 hours against about 3 hours for the tablet
- **Initial Dose:**
  - 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, 6-16 y/o: 5 mg at weekly intervals
    - Narcolepsy, 6-11 y/o: 5 mg at weekly intervals
    - Narcolepsy, ≥ 12 y/o: 10 mg at weekly intervals
- **Max Dose:**
    - ADHD: 40 mg/day; only in rare cases will it be necessary to exceed this
    - Narcolepsy: usual range 5-60 mg/day in divided doses
- **Considerations:** Use once daily where appropriate; the same total dose of immediate release in divided doses is equally effective by this label. Avoid late evening doses.

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:** Lower peak than the tablet (Cmax 23.5 vs 36.6 ng/mL at 15 mg), same bioavailability
- **Formulation:** Single-isomer dextroamphetamine sulfate; no levoamphetamine, the difference from the 3:1 mixed-salt products
- **Metabolism:** CYP2D6 to 4-hydroxyamphetamine, with minor CYP2D6 inhibition. Half-life about 12 hours. Renal excretion is pH dependent
- **Pharmacogenomics:** No genotype-directed dosing in the label; the actionable consequence is the CYP2D6-inhibitor interaction
- **Class Positioning:** Buys once-daily dosing and a lower peak over Zenzedi, and gives up the 3 to 5 year band. Single-isomer and later-peaking than Adderall XR

Indications

- **Narcolepsy** (ICD-10: G47.419): no age bound stated; dosing from age 6
- **ADHD** (ICD-10: F90.0, F90.1, F90.2, F90.8, F90.9): patients 6 to 16 y/o, within a total treatment program

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Off-Label Uses

- **ADHD at 17 and older** (ICD-10: F90.x): this label stops at 16. Supported by the broader amphetamine literature; switch to a product with an adult indication.

- **ADHD under 6 years** (ICD-10: F90.x): insufficient. Zenzedi, the same moiety, is approved from age 3, so the floor is formulation-specific. AAP: behavioral intervention first-line (AAP 2019).
- **Binge eating disorder** (ICD-10: F50.81): lisdexamfetamine holds it, adults only; insufficient here.
- **Where the evidence does not support use:** depression augmentation; no pediatric evidence for sustained-release dextroamphetamine (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 and monitor throughout.
- **Contraindicated:**
  - Known hypersensitivity 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
  - Pre-existing hypertension; expect mean rises of 2-4 mmHg and 3-6 bpm
  - Psychosis or bipolar disorder; in psychotic children, worsened behaviour disturbance and thought disorder
  - Prior seizure or EEG abnormality
  - Peripheral vasculopathy including Raynaud phenomenon
  - Tics or Tourette syndrome, personal or family
  - Substance use disorder, patient or household
  - Symptoms secondary to environmental factors or another psychiatric disorder
- **Screen before starting:**
  - Cardiac and family history of sudden death or ventricular arrhythmia; ECG only if positive
  - Tics and Tourette syndrome, in child and family; this label makes that a precondition
  - Mania risk factors, including family history of suicide or bipolar disorder
  - Abuse and diversion risk
  - Baseline height, weight, blood pressure and heart rate

Drug Interactions

- **MAOIs** (selegiline, tranylcypromine, phenelzine, linezolid, methylene blue): hypertensive crisis; do not give within 14 days.
- **Serotonergic agents** (SSRIs, SNRIs, TCAs, triptans, fentanyl, lithium, tramadol, buspirone): serotonin syndrome; counsel on symptoms and stop both if it occurs.

- **CYP2D6 inhibitors** (paroxetine, fluoxetine, quinidine, ritonavir): raise exposure; start lower.
- **Alkalinizing agents** (sodium bicarbonate, acetazolamide): raise levels; the label says avoid.
- **Acidifying agents** (ascorbic acid, methenamine salts): lower levels; adjust on response.
- **Tricyclics** (desipramine, protriptyline): sustained rise in brain d-amphetamine; monitor and adjust.
- **Antiepileptics** (phenytoin, phenobarbital, ethosuximide): delayed absorption; separate dosing and check levels after any stimulant change.
- **Antihypertensives:** hypotensive effect antagonised; recheck blood pressure after starting the stimulant.
- **Antihistamines:** sedative effect counteracted; do not rely on one for sleep.

Administration

- Give the first dose on waking; may be used once daily wherever appropriate.
- For narcolepsy the label's usual dose is divided; the Spansule may replace those divisions.
- Avoid late evening doses.
- **Swallow whole.** This label carries no instruction to open, sprinkle, crush or chew, and no data for doing so, unlike its mixed-salt siblings.
- If the child cannot swallow a capsule, switch to an IR tablet or ProCentra oral solution.
- Food does not matter; absorption is similar fed and fasted.
- The label directs prescribing the least quantity feasible at one time.
- If a dose is missed, skip it; do not double up.
- Store securely, preferably locked.

Side Effects

- **Common:** loss of appetite, weight loss, insomnia, overstimulation, restlessness, dry mouth, headache, dizziness, tremor, dysphoria, diarrhoea, constipation, palpitations, raised blood pressure
- **Serious:**
  - Sudden death with structural cardiac disease. Investigate exertional chest pain or syncope immediately.
  - Psychotic episodes at recommended doses (rare), 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. Interrupt if height or weight gain falls behind.
  - New or worsening motor and verbal tics. Discontinue if clinically appropriate.

    - Cardiomyopathy with chronic use, rhabdomyolysis, intestinal ischaemia.
    - Prolonged erections; painful erection beyond a few hours is a surgical emergency.

Monitoring & Labs

- **Cardiovascular:** heart rate and blood pressure at baseline, each dose change, and every 6 months.
- **Growth:** height, weight and BMI charted at baseline and every 6 months; interrupt if two major percentile lines are crossed.
- **Appetite and Sleep:** at every visit and dose change; ask what time the child eats and falls asleep.
- **Psychiatric and tics:** psychosis, mania, aggression, dysphoria 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; set quantity limits per this label's least-quantity instruction.
- **Age boundary:** review the indication at the 17th birthday.
- **Laboratory:** none routinely.

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.
- Rebound irritability and hunger arrive later than with the IR tablet; families describe a difficult evening.
- Interrupt treatment where growth or weight gain falls behind.
- Drug holidays are reasonable where appetite or growth suppression is limiting; unlike Zenzedi, this label does not itself recommend periodic interruption.

Pregnancy & Lactation

- **Pregnancy:** No adequate controlled studies; animal teratogenicity only far above human doses. Amphetamine-dependent mothers have more premature delivery and low birth weight. Use only if benefit justifies fetal risk.
- **Lactation:** Label advises against nursing. LactMed: infant dose about 5.7% of the maternal weight-adjusted dose, infant plasma 6 to 14% of maternal, all four infants studied growing normally. (LactMed 2025)

- **Milk supply:** Dose-related prolactin suppression up to 40% may impair production before lactation is established. (LactMed 2025)
- **Exposure Registry:** None on this label; the National Pregnancy Registry for Psychostimulants (1-866-961-2388) accepts amphetamine exposures.

Counseling Points

- **Counsel the family on:**
  - Swallowing the capsule whole; unlike the mixed-salt capsules there is no sprinkle instruction.
  - Telling you if the child cannot swallow it, so the product changes rather than being improvised.
  - The capsule being a convenience, not an upgrade; divided immediate release works as well.
  - The later peak, around eight hours, so the hard stretch is often evening rather than mid-afternoon.
  - Vitamin C mimicking treatment failure; bicarbonate and antacids raising levels.
  - On phenytoin, phenobarbital or ethosuximide, a level check after a stimulant change is expected.
  - Moving the largest meal to breakfast and evening, with a weight check each visit.
  - The ADHD approval running to age 16; plan before the 17th birthday.
  - Locked storage; the prescription is deliberately written in the smallest workable quantity.
- **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.
  - Severe muscle pain with dark urine after exertion.
  - 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.
  - Agitation, shivering, sweating or confusion after an antidepressant change.

References

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