Dyanavel XR

(amphetamine)

Dyanavel XR (amphetamine); CII

Full Prescribing Information	DailyMed Drug Information

Summary

Dyanavel XR is an extended-release amphetamine supplied as an oral suspension and as an extended-release tablet under one label, approved for ADHD from age 6. The moiety is amphetamine in a 3.2:1 d- to l- ratio, dosed in amphetamine base rather than salt, with immediate- and extended-release components for once-daily morning dosing. Its differentiator is being the only full-day amphetamine available as a true liquid. Schedule II; brand only.

Forms & Strengths

- **Extended-release oral suspension** (bubblegum; 60 mL and 464 mL bottles): 2.5 mg/mL
- **Extended-release tablets** (5 mg scored; may be chewed): 5 mg, 10 mg, 15 mg, 20 mg

Dosing

- **Age:** ≥ 6 y/o
- **Onset:** ~ 1 hour
- **Duration:** up to 13 hours
- **Release Profile:** combined immediate-release and extended-release components; this label publishes no percentage split
- **Initial Dose:** 2.5 mg or 5 mg once daily in the morning, all patients ≥ 6
- **Titration:** 2.5 mg to 10 mg per day every 4 to 7 days
- **Max Dose:** 20 mg once daily

- **Considerations:** Suspension and tablet substitute milligram for milligram; no other amphetamine does, because these strengths are base rather than salt. Titrate from scratch when switching in.

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:** Ion-exchange resin supplies the extended fraction, amphetamine aspartate and dextroamphetamine sulfate the immediate. Median Tmax ~4 h (suspension), ~5 h (tablet)
- **Formulation:** 3.2:1 d- to l-amphetamine, all strengths as amphetamine base; the critical fact when converting in
- **Metabolism:** CYP2D6 forms active 4-hydroxyamphetamine; norephedrine also active. Half-life 12.4 h d- and 15.1 h l- in adults, 10.4 h and 12.1 h in children 6-12; urinary recovery is pH dependent
- **Pharmacogenomics:** CYP2D6 is polymorphic; no genotype-based adjustment specified, so titrate slowly rather than genotype
- **Class Positioning:** Against Adderall XR, a 3.2:1 rather than 3:1 ratio, base rather than salt dosing, 13 hour ceiling; against Adzenys XR-ODT, also base-dosed, it is the option when nothing solid is accepted
- **Impairment:** renal and hepatic impairment unstudied for this product; both may prolong exposure

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Indications

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

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Off-Label Uses

- **None established.** One indication, and no off-label use of this formulation is supported by graded pediatric evidence.
- **Where the evidence does not support use:**
  - **Children under 6:** argued against by this label; the liquid makes small doses easy to give, which is why this needs saying.
  - **Non-ADHD indications in youth:** AHRQ CER 267 graded none; insufficient (AHRQ 2024).
  - **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 non-oral routes. Assess risk before prescribing; reassess throughout.
- **Contraindicated:**
  - Known hypersensitivity to amphetamine or components; angioedema and anaphylaxis reported
  - MAOI use, current or within 14 days, including linezolid and IV methylene blue
- **Use with caution** (Warnings in this label, not contraindications):
  - Structural cardiac abnormality, cardiomyopathy, serious arrhythmia or coronary disease; label says avoid, for sudden death
  - Pre-existing hypertension, because BP and HR rise
  - Pre-existing psychosis; bipolar disorder, for treatment-emergent mania
  - Motor or verbal tics, or Tourette syndrome
  - Peripheral vasculopathy including Raynaud phenomenon
  - Renal or hepatic impairment; unstudied for this product, and both may prolong exposure
  - 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) lower amphetamine levels; alkalinizers (bicarbonate, acetazolamide, thiazides) raise them. The label directs an explicit dose adjustment either way.
- **Sympathomimetics** (decongestants, beta-agonists): additive cardiovascular effect. Avoid OTC decongestants.
- **Laboratory assays:** amphetamines elevate plasma corticosteroids and interfere with urinary steroid determinations; interpret rather than repeat.

Administration

- Once daily in the morning, with or without food; a high-fat meal changes exposure only a few percent.
- **Suspension:** shake hard before every dose; keep the bottle adapter inserted and measure with the pharmacy dispenser.
- **Tablet:** may be chewed or swallowed whole, with no significant change in exposure or Tmax; only the 5 mg is scored.
- **Between the two Dyanavel XR forms:** substitute milligram for milligram, the only such substitution the label permits.
- **From any other amphetamine:** stop the previous drug and titrate from the beginning.
- Avoid late dosing; with a 13 hour ceiling an afternoon dose reaches bedtime.
- Store securely, preferably locked.

Side Effects

- **Common** (extended-release amphetamine class list, per this label): decreased appetite and weight loss, insomnia, irritability, abdominal pain, dry mouth, headache, tremor, restlessness, bowel change, palpitations, tachycardia, elevated blood pressure.
- **Serious:**
  - Sudden death, myocardial infarction and stroke 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.
  - Angioedema, anaphylaxis, Stevens-Johnson syndrome and toxic epidermal necrolysis; stop and do not rechallenge.
  - Peripheral vasculopathy including Raynaud phenomenon, with digital ulceration reported; 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.
  - 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.
- **Growth:** height, weight and BMI charted at baseline and every 6 months; interrupt if crossing two major percentile lines.

- **Appetite and sleep:** every visit; with a 13 hour ceiling, sleep is what most often forces a timing change here.
- **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.
- **Dosing technique:** watch the caregiver shake and draw a dose at first follow-up and whenever response turns erratic; an unshaken bottle looks like tolerance.
- **Abuse and diversion:** adherence, bottle or pill counts and PDMP check at each refill.
- **Laboratory:** none routinely required.

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.
- Late-evening rebound irritability and hunger is pharmacodynamic offset, not withdrawal.
- Drug holidays suit appetite or growth as the limiting problem, less so a child who struggles outside school hours.

Pregnancy & Lactation

- **Pregnancy:** Published data are insufficient to determine a drug-associated risk of major malformations or miscarriage. Amphetamines vasoconstrict placental vessels, may increase growth restriction, and stimulate uterine contractions.
- **Pregnancy, clinical:** premature delivery and low birth weight in dependent mothers; background risk is 2% to 4% for major defects and 15% to 20% for miscarriage. Weigh rather than abstain.
- **Neonate:** monitor for feeding difficulty, irritability, agitation and drowsiness.
- **Lactation:** present in milk at relative infant doses of 2% to 13.8%, milk to plasma 1.9 to 7.5. No reported adverse infant effects; long-term neurodevelopment unknown; the label does not recommend breastfeeding.
- **Lactation, practical:** some experts accept therapeutic doses, monitoring the infant for irritability, insomnia and feeding difficulty; prolactin is suppressed 25% to 40%. (LactMed 2025)
- **Exposure Registry:** National Pregnancy Registry for Psychostimulants, 1-866-961-2388, https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/othermedications/

Counseling Points

- **Counsel the family on:**
  - Shaking the suspension hard before every dose; an unshaken bottle is the commonest cause of a Dyanavel XR that works some days and not others.
  - That the tablet may be chewed, which often solves swallowing without moving to the liquid.
  - The roughly 13 hour window, so a dose after mid-morning still works at bedtime.
  - Appetite suppression peaking midday; largest meal at breakfast and in the evening.
  - Never converting from a previous amphetamine milligram for milligram.
  - Storing the bottle locked, not with the other syrups; the bubblegum flavour is a formulation property.
  - Bringing a teacher rating scale to the next visit rather than a verbal impression.
- **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.
  - Swelling of the lips, tongue or face, or any spreading rash or blistering.
  - Numbness, coldness or colour change in the fingers or toes.
  - A new or markedly worse tic; weight loss or clothes fitting more loosely.
  - A painful erection lasting more than a few hours.

References

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