Mydayis

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

Mydayis (mixed salts of a single-entity amphetamine product); CII

Full Prescribing Information	DailyMed Drug Information

Summary

Mydayis is a triple-bead extended-release amphetamine capsule approved for ADHD from age 13, carrying the same four salts and 3:1 dextro to levo ratio as Adderall XR. An immediate-release bead plus two delayed-release beads unlocking at pH 5.5 and pH 7.0 give the longest coverage of any oral amphetamine here. Choose it when an adolescent needs late-evening rather than school-day coverage; it is ruled out below 13, where no safe and effective dose could be established. Schedule II; brand and generic.

Forms & Strengths

- **Extended-release capsules:** 12.5 mg, 25 mg, 37.5 mg, 50 mg

Dosing

- **Age:** ≥ 13 y/o; not established at 12 years and younger
- **Onset:** 2-4 hours to measurable effect
- **Duration:** up to 16 hours

- **Release Profile:** Triple bead; one immediate-release plus two delayed-release beads releasing at pH 5.5 and pH 7.0. Tmax 7-10 hours pediatric, about 8 hours adult
- **Initial Dose:**
  - 13-17 y/o: 12.5 mg once daily on awakening
  - 18-55 y/o: 12.5 mg once daily on awakening; 25 mg may be considered
  - Severe renal impairment (GFR 15 to < 30), adults: 12.5 mg once daily. ESRD not recommended at any age
- **Titration:** 12.5 mg no sooner than weekly, at any age
- **Max Dose:**
  - 13-17 y/o: 25 mg/day; above 25 mg not evaluated in pediatric trials. Severe renal impairment: 12.5 mg/day
  - 18-55 y/o: 50 mg/day; no additional benefit above 50 mg. Severe renal impairment: 25 mg/day
  - No dosing recommendation above age 55
- **Considerations:** Give on awakening; effect may last 16 hours. Take consistently with or without food, since a high-fat meal delays Tmax 4.5 to 5 hours. A missed dose is skipped.

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:** Two pH triggers rather than a timed matrix stage the second and third releases down the gut
- **Formulation:** Four salts in equal weight, 3:1 dextro to levo. Linear over 12.5 to 50 mg, steady state days 7 to 8
- **Metabolism:** CYP2D6 to 4-hydroxyamphetamine. Half-life 10-11 h d-amphetamine, 10-13 h l-amphetamine. Renal excretion is pH dependent
- **Pharmacogenomics:** No genotype-directed dosing in the label; the actionable consequence is the CYP2D6-inhibitor interaction
- **Class Positioning:** Same salts as Adderall XR plus a third pH 7.0 bead, extending 12 hours to 16, at the cost of the age-13 floor. Uniquely pH-dependent, so alkalinizers and PPIs matter more

---

Indications

- **ADHD** (ICD-10: F90.0, F90.1, F90.2, F90.8, F90.9): patients ≥ 13 y/o. The only approved indication.

Off-Label Uses

- **ADHD in children 6 to 12** (ICD-10: F90.x): studied in two trials and rejected; negative on dose-finding. Use Adderall XR instead.
- **Narcolepsy** (ICD-10: G47.419): off-label at every age; insufficient. Use an approved product: Adderall, Zenzedi, Dexedrine Spansule.
- **Binge eating disorder** (ICD-10: F50.81): lisdexamfetamine holds this indication, adults only; insufficient here.
- **Where the evidence does not support use:** depression augmentation; no pediatric evidence for triple-bead mixed salts (AHRQ 2024).
- **Cognitive enhancement without ADHD:** not an indication; not supported.

Contraindications & Warnings

- **Boxed Warning:** Abuse, misuse, and addiction; misuse can cause overdose and death. Assess abuse risk before prescribing and monitor frequently throughout.
- **Contraindicated:**
  - Known hypersensitivity to amphetamine products or any ingredient in Mydayis
  - 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; blood pressure and heart rate rise
  - Psychosis or bipolar disorder
  - Prior seizure or EEG abnormality
  - Peripheral vasculopathy including Raynaud phenomenon
  - Tics or Tourette syndrome, personal or family
  - Substance use disorder, patient or household
  - Severe renal impairment; start and maximum both halve, ESRD not recommended
  - Settings where substitution error is likely; the label carries a dedicated overdose warning
- **Screen before starting:**
  - Cardiac and family history of sudden death or ventricular arrhythmia; ECG only if positive
  - Tics, Tourette syndrome and mania risk factors, including family history
  - Abuse and diversion risk
  - Baseline height, weight, blood pressure and heart rate
  - Baseline sleep pattern, before adding a 16-hour agent

Drug Interactions

- **MAOIs** (phenelzine, tranylcypromine, selegiline, linezolid, IV methylene blue): hypertensive crisis; do not give within 14 days.
- **Serotonergic agents** (SSRIs, SNRIs, TCAs, triptans, fentanyl, lithium, tramadol, buspirone, St John's Wort): serotonin syndrome; counsel on symptoms and stop both if it occurs.
- **CYP2D6 inhibitors** (fluoxetine, paroxetine, bupropion, quinidine): raise exposure; start lower and monitor at each increase.
- **Alkalinizing agents** (sodium bicarbonate, acetazolamide): raise levels and can unlock the beads early; avoid.
- **Acidifying agents** (ascorbic acid, fruit juices): lower levels; adjust on response, not assumed failure.
- **Proton pump inhibitors** (omeprazole): raise gastric pH and shift Tmax earlier; adjust timing.
- **Alcohol:** in vitro, 20% and especially 40% alcohol increased release from the capsule; counsel on dose dumping.

Administration

- Once daily on awakening; up to 16 hours of effect means later dosing costs sleep.
- Take consistently with food or without, never alternating.
- Swallow whole, or sprinkle the entire contents on applesauce, eaten immediately without chewing. Do not store.
- Do not divide a capsule; sprinkling is a swallowing accommodation, not a dose split.
- If a dose is missed, skip it and resume the next morning; never make it up.
- Switching from another amphetamine: stop it and titrate from 12.5 mg weekly. No milligram-for-milligram conversion exists.
- Store securely, preferably locked.

Side Effects

- **Common, 13 to 17:** decreased appetite 22%, insomnia 8%, nausea 8%, irritability 6%, decreased weight 5%, dizziness 4%, upper abdominal pain 4%
- **Common, adults:** insomnia 31%, decreased appetite 30%, weight decreased 9%, anxiety 7%, depression 3%, bruxism 2%
- **Serious:**
  - Sudden death with structural cardiac disease. Investigate exertional chest pain or syncope immediately.
  - Psychosis, 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.
    - Overdose from substitution error between amphetamine products.

Monitoring & Labs

- **Cardiovascular:** heart rate and blood pressure at baseline, each dose change, and every 6 months; act above the age-specific 95th percentile.
- **Growth:** height, weight and BMI charted at baseline and every 6 months; interrupt if the adolescent crosses two major percentile lines.
- **Sleep:** at every visit and dose change, asking specifically about sleep-onset latency.
- **Appetite and weight:** at every visit and every dose change.
- **Psychiatric and tics:** psychosis, mania, aggression, irritability 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.
- **Renal function:** at baseline where impairment is suspected, and annually.
- **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 land late in the evening with a 16-hour agent, not after school.
- Interrupt treatment where growth or weight gain falls behind.
- Drug holidays fit poorly here; where appetite or growth is limiting, switch to a shorter product instead.

Pregnancy & Lactation

- **Pregnancy:** Data insufficient to inform a risk of major birth defects or miscarriage. Premature delivery and low birth weight reported. Monitor exposed newborns for withdrawal.
- **Lactation:** Label says breastfeeding is not recommended. Relative infant dose 2 to 13.8%, milk/plasma ratio 1.9 to 7.5; no reported infant adverse effects.
- **Milk supply:** Dose-related prolactin suppression up to 40% may impair production before lactation is established. (LactMed 2025)

- **Exposure Registry:** National Pregnancy Registry for Psychiatric Medications, 1-866-961-2388.

Counseling Points

- **Counsel the family on:**
  - The 16-hour duration is both the reason for choosing it and the reason to watch sleep in week one.
  - Dosing on waking every day and never taking a missed dose later; a noon dose is a sleepless night.
  - Taking it the same way daily, with or without food, because switching moves the peak by about five hours.
  - Alcohol releases amphetamine faster from this capsule in laboratory testing.
  - Antacids and reflux medicines change when the later beads open, because they unlock on gut pH.
  - Never swapping this for another amphetamine capsule at the same milligrams; Mydayis 37.5 mg is not Adderall XR 37.5 mg.
  - Sprinkling being a swallowing accommodation, not a dose split.
  - Locked storage; sharing or selling a Schedule II medication is a felony.
- **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.
  - Falling asleep after 1 am on more than a night or two.
  - Weight loss, or clothes fitting more loosely over a few weeks.
  - Agitation, shivering, sweating or confusion after an antidepressant change.

References

1. DailyMed. MYDAYIS (dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate monohydrate, and amphetamine sulfate) extended-release capsules prescribing information. Takeda Pharmaceuticals America. Revised 4/2026. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=141a7970-3f06-44ea-9ab7-aeece2c085fc
2. LactMed. Amphetamine. Drugs and Lactation Database, National Institute of Child Health and Human Development. 2025. https://www.ncbi.nlm.nih.gov/books/NBK501307/
3. openFDA. NDC Directory, generic_name "amphetamine aspartate". US Food and Drug Administration. 2026. https://api.fda.gov/drug/ndc.json
4. Agency for Healthcare Research and Quality. ADHD Diagnosis and Treatment in Children and Adolescents. Comparative Effectiveness Review No. 267. 2024. https://www.ncbi.nlm.nih.gov/books/NBK602989/

Revision #25
Created 2024-12-21 13:53:03 UTC by Josh LeJeune NP
Updated 2026-08-20 06:46:06 UTC by Josh LeJeune NP