Vyvanse

(lisdexamfetamine dimesylate)

Vyvanse (lisdexamfetamine dimesylate); CII

Full Prescribing Information	DailyMed Drug Information

Summary

Vyvanse is a long-acting amphetamine prodrug approved for ADHD from age 6 and for moderate to severe binge eating disorder in adults only. It is pharmacologically inert until red blood cells hydrolyse it to dextroamphetamine, so its onset is governed by that conversion rather than by a coating, a bead or a matrix. That single property is its differentiator: there is no release mechanism to defeat by crushing, chewing or dissolving, and capsule and chewable tablet interchange milligram for milligram. Schedule II; brand and generic.

Forms & Strengths

- **Capsules:** 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg
- **Chewable tablets:** 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg
- **Oral solution** (Arynta, a separate NDA product): 10 mg/mL

Dosing

- **Age:**
  - ADHD: ≥ 6 y/o; not recommended below 6 years
  - Binge eating disorder: ≥ 18 y/o only; not established under 18
- **Onset:** 1.5-2 hours
- **Duration:** 13-14 hours
- **Release Profile:** None. Inactive prodrug hydrolysed by red blood cells; Tmax about 3.5 h from the capsule, 4.4 h from the chewable
- **Initial Dose:**

    - ADHD, ≥ 6 y/o and adults: 30 mg once daily in the morning
    - BED, adults: 30 mg once daily in the morning
- **Titration:**
    - ADHD: 10 mg or 20 mg at approximately weekly intervals
    - BED: 20 mg at approximately weekly intervals, to a target of 50 to 70 mg/day
- **Max Dose:**
    - ADHD and BED: 70 mg/day
    - Severe renal impairment (GFR 15 to < 30): 50 mg/day
    - End stage renal disease (GFR < 15): 30 mg/day
- **Considerations:** Give in the morning; avoid afternoon doses. Capsule and chewable substitute milligram for milligram, but there is no 70 mg chewable.

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
- **Prodrug:** Dextroamphetamine bound to L-lysine, inactive as swallowed; the parent does not bind DAT or NET
- **Delivery / Release:** None. Hydrolysis in blood means crushing, chewing or dissolving does not accelerate it
- **Metabolism:** Not metabolised by CYP450. Prodrug half-life under 1 hour; dextroamphetamine 8.6-9.5 h in children 6-12, 10-11.3 h in adults
- **Pharmacogenomics:** Activation is CYP-independent; downstream clearance still involves CYP2D6. No genotype-directed dosing
- **Class Positioning:** No bead, coating or pH trigger, so gut pH and PPIs matter far less than for Adderall XR or Mydayis. Shorter than Mydayis but available from age 6

Indications

- **ADHD** (ICD-10: F90.0, F90.1, F90.2, F90.8, F90.9): patients ≥ 6 y/o and adults
- **Moderate to severe binge eating disorder** (ICD-10: F50.81): adults ≥ 18 y/o only
- **Limitation of Use:** not indicated for weight loss or obesity

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Off-Label Uses

- **Binge eating disorder in adolescents** (ICD-10: F50.81): insufficient. Document and consent as off-label if used.

- **Narcolepsy** (ICD-10: G47.419): off-label at every age; insufficient. Use an approved product: Adderall, Zenzedi, Dexedrine Spansule.
- **Depression augmentation** (ICD-10: F33.x): studied as adjunct in adult MDD, indication not granted; insufficient.
- **ADHD under 6 years** (ICD-10: F90.x): studied and rejected; weight loss and insomnia at exposures 44% above the 6-11 band. AAP names behavioral intervention first-line (AAP 2019).
- **Cognitive enhancement or weight loss:** not indications; weight loss is explicitly excluded by the label (AHRQ 2024).

Contraindications & Warnings

- **Boxed Warning:** Abuse, misuse, and addiction; misuse can cause overdose and death. Assess abuse risk before prescribing and monitor throughout. The prodrug design does not exempt this product.
- **Contraindicated:**
  - Known hypersensitivity to amphetamine products or any ingredient in Vyvanse
  - MAOI use, current or within 14 days
- **Use with caution** (label Warnings, not contraindications):
  - Structural cardiac abnormality or serious arrhythmia; the label says avoid
  - Pre-existing hypertension; blood pressure and heart rate rise
  - Psychosis or bipolar disorder
  - Peripheral vasculopathy including Raynaud phenomenon
  - Tics or Tourette syndrome, personal or family
  - Substance use disorder, patient or household
  - Renal impairment; maximum 50 mg severe, 30 mg ESRD
  - Restrictive eating features, where appetite suppression is reinforcing
- **Screen before starting:**
  - Cardiac and family history of sudden death; ECG only if positive
  - Tics, Tourette syndrome and mania risk factors
  - Abuse and diversion risk
  - Baseline height, weight, blood pressure and heart rate
  - Eating attitudes and restrictive or purging behaviour

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): serotonin syndrome; counsel on symptoms and stop both if it occurs.

- **CYP2D6 inhibitors** (fluoxetine, paroxetine, bupropion, quinidine): raise dextroamphetamine exposure, though not prodrug activation; start lower.
- **Alkalinizing agents** (sodium bicarbonate, acetazolamide): raise levels by reducing renal elimination; adjust the dose.
- **Acidifying agents** (high-dose ascorbic acid, ammonium chloride): lower levels; adjust on response. Orange juice as a dispersal vehicle does not change exposure.

Administration

- Once daily in the morning, with or without food; afternoon doses cost sleep.
- Swallow whole, or empty the entire contents into yogurt, water or orange juice, mix and drink immediately. Do not store.
- A film left in the glass is inactive ingredient, not lost drug.
- Chewable tablets must be chewed thoroughly.
- Capsule and chewable substitute milligram for milligram with no re-titration; 70 mg exists only as a capsule.
- Do not take less than one capsule or tablet daily; do not divide a dose.
- A high-fat meal delays Tmax by about an hour without changing absorption.
- If a dose is missed, skip it; do not double up.
- Store securely, preferably locked; the prodrug limits snorting and injection but does not make diversion safe.

Side Effects

- **Common, 6 to 12:** decreased appetite 39%, insomnia 22%, upper abdominal pain 12%, irritability 10%, vomiting 9%, decreased weight 9%, dizziness 5%, tic 2%
- **Common, 13 to 17:** decreased appetite 34%, insomnia 13%, decreased weight 9%, dry mouth 4%, palpitations 2%, tremor 2%
- **Serious:**
  - Sudden death with structural cardiac disease. Investigate exertional chest pain or syncope immediately.
  - Psychosis, mania and new aggression. Consider discontinuing.
  - Serotonin syndrome, from coadministration or overdose. Stop both drugs and treat supportively.
  - 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.

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 the child crosses two major percentile lines.
- **Appetite and Sleep:** at every visit and dose change; ask about sleep-onset latency and midday intake.
- **Psychiatric and tics:** psychosis, mania, aggression, affect lability 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.
- **Eating behaviour** where BED or restrictive features exist: at every visit.
- **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 in the evening, not after school.
- In BED, the label instructs discontinuing if binge eating does not improve; apply that stopping rule.
- Interrupt treatment where growth or weight gain falls behind.
- Drug holidays work better here; restarting needs no re-titration.

Pregnancy & Lactation

- **Pregnancy:** No identified 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%; no reported infant adverse effects.
- **Lactation, drug-specific:** Two small series found colic, restlessness and delayed birthweight regain in a minority, with normal follow-up. (LactMed 2026)
- **Milk supply:** Dose-related prolactin suppression up to 40% may impair production before lactation is established. (LactMed 2026)
- **Exposure Registry:** National Pregnancy Registry for Psychostimulants, 1-866-961-2388.

Counseling Points

- **Counsel the family on:**
  - The capsule does nothing until the body converts it, so effect starts around 90 minutes.
  - Emptying it into water, yogurt or juice is a complete option for a child who cannot swallow capsules.
  - Capsule and chewable interchange milligram for milligram, except that no 70 mg chewable exists.
  - The prodrug makes snorting or injection harder; it does not make sharing safe.
  - Appetite loss 39% at ages 6 to 12, the highest here. Move the largest meal to breakfast and evening.
  - Where a family has heard Vyvanse "treats binge eating": adults only, never for weight loss.
  - Locked storage; sharing or selling a Schedule II medication is a felony.
  - Bring 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, coldness or colour change in the fingers or toes.
  - A new or markedly worse tic, motor or verbal.
  - Weight loss, or a child eating nothing between breakfast and dinner.
  - New meal skipping, hiding food, or a stated wish to lose weight.
  - Agitation, shivering, sweating or confusion after an antidepressant change.

References

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