Xelstrym

(dextroamphetamine)

Xelstrym (dextroamphetamine); CII

Full Prescribing Information	DailyMed Drug Information

Summary

Xelstrym is a dextroamphetamine transdermal system, the only amphetamine patch on the U.S. market, approved for ADHD from age 6 and worn up to 9 hours a day. It delivers single-entity d-amphetamine through the skin, bypassing swallowing and letting a caregiver end the exposure early by removing the patch. That reversibility is its differentiator; its cost is the skin, where irritation and discomfort were near-universal. Schedule II; brand only.

Forms & Strengths

- **Transdermal system** (9 hour wear; dose set by patch area): 4.5 mg/9 h, 9 mg/9 h, 13.5 mg/9 h, 18 mg/9 h

Dosing

- **Age:** ≥ 6 y/o
- **Onset:** ~ 2 hours
- **Duration:** up to 12 hours
- **Release Profile:** continuous transdermal delivery, about 90% of content over 9 hours; peak plasma at 6 to 9 hours, ~6 hours on repeat
- **Initial Dose:**
  - 6-17 y/o: 4.5 mg/9 h daily
  - ≥ 18 y/o: 9 mg/9 h daily
- **Titration:** 4.5 mg/9 h every 7 days, patients 6-17
- **Max Dose:**

    - All ages: 18 mg/9 h, one system per 24 hours
    - Severe renal impairment, GFR 15 to under 30 mL/min/1.73 m²: 13.5 mg/9 h
    - End-stage renal disease, GFR under 15 mL/min/1.73 m²: 9 mg/9 h
- **Considerations:** Apply 2 hours before effect is needed, remove within 9 hours, and use a shorter wear to shorten the day. Rotate sites daily, never cut a patch, and keep external heat off it.

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:** Dextroamphetamine in an acrylic adhesive matrix; absorption tracks wear time and area, not site, with 20% to 30% variability
- **Formulation:** d-isomer only, unlike Adderall or Evekeo
- **Metabolism:** CYP2D6, polymorphic, forms active 4-hydroxyamphetamine. Half-life after a 9 hour wear is 6.4 h in children, 11.5 h in adults; not dialyzable, hence the ESRD cap
- **Class Positioning:** the only amphetamine whose exposure can be curtailed mid-day; the cost is daily adhesive on skin and a 1.5-fold rise under heat. Daytrana is methylphenidate, not interchangeable

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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** for this formulation by graded pediatric evidence.
- **Where the evidence does not support use:**
    - **Children under 6:** argued against by this label.
    - **Wear beyond 9 hours:** a dose increase without a dose change.
    - **Cutting a patch:** forbidden.
    - **Non-ADHD indications, and cognitive enhancement without ADHD:** AHRQ CER 267 graded none (AHRQ 2024).

Contraindications & Warnings

- **Boxed Warning:** Abuse, misuse, and addiction. High abuse potential leading to substance use disorder; overdose and death, more so at higher doses. Assess risk before prescribing; reassess throughout.
- **Contraindicated:**
  - Known hypersensitivity to amphetamine or components
  - MAOI use, current or within 14 days, including linezolid and IV methylene blue
- **Contact sensitization:** suspect it if erythema comes with edema, papules or vesicles that fail to improve within 48 hours or spread beyond the site. Discontinue.
- **Its consequence is not local:** a sensitized patient may be unable to take amphetamine in ANY form.
- **Use with caution** (Warnings, not contraindications):
  - Structural cardiac abnormality, cardiomyopathy, serious arrhythmia or coronary disease; label says avoid
  - Hypertension; psychosis; bipolar disorder; tics or Tourette syndrome; Raynaud phenomenon
  - Dermatitis, eczema or fragile skin at candidate sites
  - Regular external heat at the site (see Interactions)
  - Severe renal impairment and ESRD, capping the dose at 13.5 and 9 mg/9 h
  - Substance use disorder in the household; a worn patch is removable by anyone
- **Screen before starting:** cardiac and family cardiac history with exam; tic history; skin at candidate sites and any prior adhesive reaction.
- **Also screen:** renal function, which sets the ceiling; abuse and diversion risk; baseline height, weight, BP, HR.

Drug Interactions

- **MAOIs** (also linezolid, IV methylene blue): hypertensive crisis. Confirm a 14 day washout before the first patch.
- **Serotonergic agents** (SSRIs, SNRIs, TCAs, triptans, lithium, tramadol): serotonin syndrome. Start lower; remove the patch and stop the other agent if symptoms appear.
- **CYP2D6 inhibitors** (paroxetine, fluoxetine, quinidine): raise exposure and serotonin syndrome risk. Prefer an alternative; else start lower.
- **Urinary pH agents:** acidifiers lower levels; alkaline urine raises exposure. Adjust strength by clinical response.
- **External heat** is a pharmacokinetic interaction: a heating pad over the system for 6 hours raised Cmax to about 116% and AUC to about 150%. Instruct explicitly against it.
- **Sympathomimetics:** additive cardiovascular effect; avoid OTC decongestants.

Administration

- One system per 24 hours, applied 2 hours before effect is needed and removed within 9 hours.
- **Early removal is a legitimate dose adjustment:** absorption tracks wear time, so it answers an evening appetite or sleep problem.
- Clean, dry, intact skin free of lotion or oil: hip, upper arm, chest, upper back or flank. Rotate daily; 28 days on one adult site raised Cmax 86% against 46% with rotation.
- Avoid touching the adhesive side. Press a lifting edge down, replace one that falls off, and never tape, cut or trim.
- A used system still contains drug; dispose of it as a Schedule II item.
- **From any other amphetamine:** stop the previous drug and titrate from the starting strength.

Side Effects

- **Common,** 6-17, dose optimization: decreased appetite 54%, insomnia 32%, headache 21%, irritability, abdominal pain and affect lability 16% each, site pain 13%, nausea 9%, fatigue 5%.
- **Application site reactions are near-universal and are the defining tolerability issue:** at double-blind clinic assessment, irritation 94% vs 54% placebo, any discomfort 69% vs 9%, severe 10% vs 4%.
- **What to tell them:** pain, itch, burning, erythema and edema during or just after wear; discomfort resolves in 2 to 4 hours, and nobody in the pediatric study stopped for it.
- **Serious:**
  - Contact sensitization, which may end the ability to take amphetamine in any form.
  - Sudden death with structural cardiac abnormality or serious cardiac disease; avoid rather than monitor.
  - Psychosis or mania, roughly 0.1% in pooled stimulant trials, and serotonin syndrome; remove the patch, stop any serotonergic agent, consider discontinuing.
  - Anaphylaxis, angioedema, urticaria, Stevens-Johnson syndrome; stop and do not rechallenge.
  - Peripheral vasculopathy with digital ulceration; growth suppression, mean weight falling over the 7 week trial; new or worsening tics, 2% vs 0%.

Monitoring & Labs

- **Application sites:** inspect at every visit and at 2 weeks, when irritation peaks; ask whether a site is being reused.
- **Contact sensitization:** apply the criteria above at any visit where erythema is reported.
- **Cardiovascular:** HR and BP at baseline, each dose change, and every 6 months.
- **Growth, appetite and sleep:** height, weight and BMI charted at baseline and every 6 months; appetite and sleep every visit. The first response to insomnia is earlier removal.

- **Psychiatric and tics:** psychosis, mania, aggression, affect lability and tics at each visit and 2 weeks after any increase; inspect the digits.
- **Renal function:** at baseline and whenever GFR could change, since the ceiling drops to 13.5 then 9 mg/9 h.
- **Abuse and diversion:** adherence, patch counts and PDMP check at each refill; used patches retain drug. No routine labs.

Discontinuation & Taper

- Can be stopped abruptly; no taper required.
- Offset is not immediate on removal; half-life after a 9 hour wear is 6.4 h in children, up to 11.5 h in adults.
- Physical dependence is labelled; withdrawal is dysphoria, depression, fatigue, vivid dreams, sleep change, increased appetite.
- Drug holidays are easy: a holiday is a day without a patch.
- **If stopped for contact sensitization, do not simply switch to an oral amphetamine.** Some sensitized patients cannot take amphetamine at all.

Pregnancy & Lactation

- **Pregnancy:** Published data have not identified a drug-associated risk of major birth defects or miscarriage; background risk is 2% to 4% and 15% to 20%.
- **Pregnancy, clinical:** amphetamines vasoconstrict, may reduce placental perfusion and stimulate contractions; premature delivery and low birth weight are reported.
- **Neonate:** monitor for withdrawal: feeding difficulty, irritability, agitation, drowsiness.
- **Lactation:** in milk at relative infant doses of 2% to 13.8%, milk to plasma 1.9 to 7.5; the label does not recommend breastfeeding.
- **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)
- **Exposure Registry:** National Pregnancy Registry for Psychiatric Medications, ADHD arm, 1-866-961-2388, https://womensmentalhealth.org/research/pregnancyregistry/adhd-medications/

Counseling Points

- **Counsel the family on:**
  - That the skin under the patch will almost certainly be red, often itchy or stinging, and that this is expected rather than an allergy.

    - The numbers, out loud: most children had irritation, about one in ten severely, and none stopped for it. Warned in advance, families get through week one.
    - That discomfort settles within 2 to 4 hours; apply 2 hours before it is needed, so before breakfast on a school morning.
    - Daily site rotation, since reusing one spot hurts more and delivers more drug.
    - That early removal shortens the day, but effect fades over hours rather than at removal.
    - No heat over the patch, no touching the sticky side, and never cutting one.
    - That a used patch still contains medication and is disposed of as a controlled substance.
- **Advise them to call for:**
    - Redness under the patch with swelling, bumps or blisters, or that does not settle within two days or spreads outside the outline; any rash elsewhere on the body.
    - 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 tic; weight loss; a patch that fell off and cannot be found.

References

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