Kapvay

(clonidine hydrochloride, extended release)

Kapvay (clonidine hydrochloride extended-release tablets); not controlled

Full Prescribing Information	DailyMed Drug Information

Summary

Kapvay is extended-release clonidine, a central alpha-2 adrenergic agonist and the first clonidine product approved for ADHD, in patients 6 to 17 years, as monotherapy or added to a stimulant. The tablet flattens the peak of immediate-release clonidine and is given twice daily, with the equal or larger share at bedtime. It is the choice when hyperactivity, impulsivity, tics or sleep onset dominate and a stimulant alone is not enough. Not controlled; the brand is no longer marketed, and generic supplies the product.

Forms & Strengths

- **Tablets, extended release:** 0.1 mg only, unscored
- **No 0.2 mg or 0.3 mg extended-release tablet exists.** Those are immediate-release strengths

Dosing

- **Age:** 6-17 y/o; not established below 6 years
- **Onset:** sedation within hours; ADHD benefit over weeks, trial endpoint at 5 weeks
- **Duration:** dosed twice daily, about 12 hours apart; half-life about 12.6 hours
- **Release Profile:** extended release; peak about 50% of immediate release, about 5 hours later, bioavailability about 89%
- **Initial Dose:** 0.1 mg at bedtime for one week

- **Titration:** 0.1 mg/day every 7 days, split twice daily with the equal or larger dose at bedtime:
  - 0.1 mg/day: 0.1 mg bedtime
  - 0.2 mg/day: 0.1 mg morning, 0.1 mg bedtime
  - 0.3 mg/day: 0.1 mg morning, 0.2 mg bedtime
  - 0.4 mg/day: 0.2 mg morning, 0.2 mg bedtime
- **Max Dose:** 0.4 mg/day as 0.2 mg twice daily; higher doses were not evaluated
- **Considerations:** Swallow whole, since the 0.1 mg tablet is unscored and crushing speeds release, so a 0.2 mg dose is two tablets and 0.4 mg/day is four. Never substitute mg-for-mg for another clonidine product, and never stop abruptly.

Pharmacology

- **Mechanism:** Central alpha-2 adrenergic agonist; reduces sympathetic outflow from the locus coeruleus and enhances prefrontal noradrenergic signalling. Mechanism in ADHD unknown.
- **Delivery / Release:** Peak about 50% of immediate release, about 5 hours later; bioavailability about 89%. Food has no effect.
- **Metabolism:** About 50% hepatic, 40% to 60% renal unchanged. Half-life about 12.6 hours in adults, up to 41 hours in severe renal impairment.
- **Pediatric exposure:** Weight-normalised clearance is higher than in adults, 23% lower in females, 11% higher with methylphenidate and **44% lower with amphetamine.**
- **Class Positioning:** Non-selective and more sedating than guanfacine (Intuniv), which is alpha-2A selective. Onyda XR shares the moiety once daily as a suspension; immediate-release clonidine is not ADHD approved.

Indications

- **ADHD, as monotherapy** (ICD-10: F90.0, F90.1, F90.2, F90.8, F90.9): patients 6-17 y/o
- **ADHD, as adjunctive therapy to stimulants** (ICD-10: F90.0, F90.1, F90.2, F90.8, F90.9): patients 6-17 y/o

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Off-Label Uses

- **Tic disorders and Tourette syndrome** (ICD-10: F95.1, F95.2): most useful with comorbid ADHD; supported by controlled trials for the class. (AACAP 2013)
- **Sleep-onset insomnia in ADHD** (ICD-10: G47.00): limited data; somnolence is a labeled adverse effect, not a demonstrated benefit

- **Where the evidence does not support use:**
  - **Children under 6** (ICD-10: F90.x): insufficient (AHRQ 2018)
  - **Oppositional defiant disorder and aggression** (ICD-10: F91.3): insufficient
  - **Anxiety and PTSD** (ICD-10: F41.x, F43.1): insufficient

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Contraindications & Warnings

- **Contraindicated:** history of hypersensitivity to clonidine, including generalised rash, urticaria or angioedema
- **Use with caution:**
  - Hypotension, heart block, bradycardia, cardiovascular or cerebrovascular disease, chronic renal failure; titrate slowly
  - Syncope, orthostatic hypotension, or a tendency to dehydration; avoid dehydration and overheating
  - Conduction abnormality or concurrent sympatholytics; severe bradycardia needing pacing reported
  - Concurrent CNS depressants, because of additive sedation
  - Renal impairment; set the initial dose by degree of impairment. Haemodialysis needs no supplemental dose
  - Prior sensitisation to the clonidine patch; oral use may cause generalised rash
- **Screen before starting:**
  - Heart rate and blood pressure, supine and standing; the label makes this mandatory
  - Syncope, palpitations, conduction disease, family history of sudden cardiac death
  - Renal function
  - Sedating and sympatholytic co-medication, including beta-blockers and digitalis

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Drug Interactions

- **Sinus node and AV nodal agents** (digitalis, calcium channel blockers, beta-blockers): additive bradycardia and AV block; label says **avoid use.** If unavoidable, check vitals each visit
- **CNS depressants** (alcohol, barbiturates, benzodiazepines, phenothiazines, sedating antihistamines): potentiated sedation; the label says **avoid use**
- **Antihypertensives:** potentiated hypotension; monitor blood pressure and adjust
- **Tricyclic antidepressants:** may counteract the hypotensive effect; monitor blood pressure and adjust
- **Amphetamine:** clonidine clearance 44% lower, so exposure is higher than with methylphenidate; titrate more cautiously and watch for sedation and bradycardia

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Administration

- Twice daily, about 12 hours apart, larger or equal share at bedtime; week 1 bedtime only
- **Swallow whole.** Do not crush, chew or break; the 0.1 mg tablet is unscored and cannot be halved
- A 0.2 mg dose is two 0.1 mg tablets, and 0.4 mg/day is four tablets a day. Write the quantity accordingly
- For a child who cannot swallow tablets, Onyda XR is extended-release clonidine as a suspension
- **Missed dose:** skip it; never exceed the prescribed daily total. Food does not matter
- **Switching:** no mg-for-mg substitution with immediate-release clonidine, Nexiclon XR or the patch; stop it and titrate from 0.1 mg
- Do not stop abruptly; see Discontinuation & Taper

Side Effects

- **Common** (monotherapy, 0.2 / 0.4 mg/day vs placebo):
  - Somnolence 38 / 31 vs 4%; fatigue 16 / 13 vs 1%; headache 20 / 13 vs 16%
  - Upper abdominal pain 15 / 10 vs 12%; irritability 9 / 5 vs 4%; nightmare 4 / 9 vs 0%
  - As adjunct: somnolence 19 vs 7%, fatigue 14 vs 4%
  - Stopped for adverse effects: 7% at 0.2 mg/day, 20% at 0.4 mg/day, vs 1% placebo
- **Serious:**
  - Rebound hypertension on abrupt discontinuation; taper
  - Dose-related hypotension and bradycardia; at 0.4 mg/day systolic fell 8.8, diastolic 7.3 mmHg, heart rate 7.7 bpm
  - Syncope; stop and check orthostatic vitals before further titration
  - Conduction abnormality or AV block; severe bradycardia has needed pacing. Obtain an ECG and stop
  - Allergic reactions including angioedema; discontinue
  - Hallucinations and QT prolongation, post-marketing; discontinue and reassess

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Monitoring & Labs

- **Heart rate and blood pressure:** baseline, 1 to 2 weeks after each increment, then every 3 months; hold titration for bradycardia by age
- **Orthostatics:** lying and standing at baseline, every dose change, and any dizziness visit
- **Sedation:** ask about school-day sleepiness at every titration visit and every visit for 3 months
- **Rebound hypertension risk:** at every refill confirm no missed doses; recheck blood pressure at each taper step

- **ADHD response:** rated scale at 5 to 8 weeks, matching the trial endpoint
- **ECG:** not routine; baseline if conduction disease, syncope history or concurrent sympatholytics, and promptly for new syncope or bradycardia
- **Renal function:** baseline and annually
- **Mood and perception:** ask about hallucinations and mood change each visit
- **Laboratory:** no routine laboratory monitoring required

Discontinuation & Taper

- **Never stop abruptly.** Reduce the total daily dose by no more than 0.1 mg every 3 to 7 days; from 0.4 mg/day that is 12 days to 4 weeks
- Abrupt cessation in adults: headache, tachycardia, nausea, flushing, chest tightness, anxiety
- With immediate-release clonidine: nervousness, agitation, tremor, and a rapid rise in blood pressure
- Even trial tapers caused events: abdominal pain 6% and raised heart rate 3% at 0.4 mg/day
- Measure blood pressure and heart rate at each taper step and after the last dose
- A vomiting illness that prevents dosing is de facto abrupt discontinuation; tell families to call
- **Drug holidays are not appropriate for this class.** Weekend and summer breaks are a rebound hypertension risk here

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Pregnancy & Lactation

- **Pregnancy:** decades of human use show no identified risk of major birth defects or miscarriage. Animal resorptions at 10x (rat) and 5x (mouse); no rabbit effect to 3x.
- **Lactation:** relative infant dose 4.1% to 8.4%; milk levels about double maternal serum. Most infants unaffected; one case of sedation, hypotonia and apnoea. Monitor for lethargy, tachypnoea and poor feeding. (LactMed 2024)
- **Lactation, milk supply:** dose-related oxytocin and prolactin effects, with postpartum galactorrhea reported. Other agents are preferred while nursing a newborn or preterm infant. (LactMed 2024)
- **Fertility:** animal studies suggest impaired fertility in both sexes
- **Exposure Registry:** National Pregnancy Registry for ADHD Medications, 1-866-961-2388, womensmentalhealth.org

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Counseling Points

- **Counsel the family on:**
  - Sleepiness in the first weeks: expected, dose related, commonest reason for stopping
  - The ADHD benefit taking weeks while sleepiness arrives on night one
  - The twice-daily schedule, larger dose at bedtime; this is not the once-daily clonidine
  - Swallowing the tablet whole, and that a 0.2 mg dose is two tablets since there is no half tablet
  - Never stopping on their own; name rebound high blood pressure in those words, and never doubling a missed dose
  - Calling if a stomach bug stops the medicine going down
  - Avoiding alcohol and sedating medicines, including antihistamines
- **Advise them to call for:**
  - Fainting, or dizziness on standing that does not settle
  - A pulse that feels very slow or irregular
  - Daytime sleepiness affecting school, or a child hard to wake
  - Severe headache with blurred vision, especially after missed doses
  - New hives, facial or lip swelling, a widespread rash, or hallucinations
  - Any vomiting illness that stops the medicine going down

References

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