Onyda XR

(clonidine hydrochloride extended-release oral suspension, 0.1 mg/mL)

Onyda XR (clonidine hydrochloride); not controlled

Full Prescribing Information	DailyMed Drug Information

Summary

Onyda XR is extended-release clonidine as an orange-flavoured oral suspension, a central alpha-2 adrenergic agonist approved for ADHD in patients 6 years and older, as monotherapy or added to a stimulant. It is the only clonidine product dosed once daily at bedtime, and the only liquid alpha-2 agonist, which is what recommends it for a child who cannot swallow tablets or who needs a dose the tablet cannot make. Not controlled; brand only, from a single manufacturer.

Forms & Strengths

- **Extended-release oral suspension (orange, light beige to tan, viscous):** 0.1 mg/mL
- Dose maps to volume: 0.1 mg is 1 mL, 0.2 mg is 2 mL, 0.3 mg is 3 mL, 0.4 mg is 4 mL

Dosing

- **Age:** 6 y/o and older; not established below 6 years
- **Onset:** sedation within hours; ADHD benefit over weeks, trial endpoint at 5 weeks
- **Duration:** once daily; clonidine half-life 12 to 16 hours, up to 41 in severe renal impairment
- **Release Profile:** clonidine complexed with sodium polystyrene sulfonate; 0.095 mg/mL resin-bound plus 0.005 mg free. Steady-state exposure close to ER tablets twice daily, trough about 26% lower

- **Initial Dose:** 0.1 mg (1 mL) once daily at bedtime, with or without food
- **Titration:** 0.1 mg/day every 7 days
- **Max Dose:** 0.4 mg (4 mL) once daily at bedtime; higher doses were not evaluated
- **Considerations:** Shake gently at least 10 seconds before every dose and measure only with the supplied dispenser. Do not substitute for any other clonidine product mg-for-mg, and never stop abruptly.

> For patients switching from another clonidine product, discontinue that treatment and titrate Onyda XR from 0.1 mg. Do not substitute milligram for milligram; the pharmacokinetic profiles differ.

Pharmacology

- **Mechanism:** Central alpha-2 adrenergic agonist; reduces sympathetic outflow from the locus coeruleus and enhances prefrontal noradrenergic signalling. Not a CNS stimulant; mechanism in ADHD unknown.
- **Delivery / Release:** Resin-complexed extended release; median Tmax 7.5 hours (range 4 to 17) against 3 to 5 for immediate release. Steady-state peak 107.9% and exposure 97.7% of ER tablets. Food has no effect.
- **Metabolism:** About 50% hepatic, 40% to 60% renal unchanged. Half-life 12 to 16 hours, up to 41 hours in severe renal impairment.
- **Alcohol and dose dumping:** in vitro, 20% alcohol produced faster and more variable release; 5% and 10% did not.
- **Class Positioning:** Non-selective, more sedating than guanfacine (Intuniv). Same pharmacology as clonidine ER tablets but once daily and measurable to any dose; IR clonidine is not ADHD approved.

Indications

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

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Off-Label Uses

- **Tic disorders and Tourette syndrome** (ICD-10: F95.1, F95.2): supported by controlled trials for the class, limited data for this product. (AACAP 2013)
- **Sleep-onset insomnia in ADHD** (ICD-10: G47.00): limited data. Somnolence is a labeled adverse effect, but this is the only clonidine whose labeled schedule is a single bedtime dose.
- **Where the evidence does not support use:**
  - **Children under 6** (ICD-10: F90.x): insufficient (AHRQ 2018), though the liquid makes dosing a preschooler easy
  - **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, 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
  - **Recurrent vomiting illness**, named in this label: missed doses raise the rebound hypertension risk
  - 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, and all sedating or sympatholytic co-medication
  - Renal function
  - Whether the family can measure a liquid dose reliably and track the discard window

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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; reduce or avoid, and counsel adolescents on

alcohol
- **Antihypertensives:** potentiated hypotension; monitor blood pressure and adjust
- **Tricyclic antidepressants:** may reduce the hypotensive effect; recheck blood pressure when either is started or stopped
- **Amphetamine:** clonidine clearance 44% lower, and 11% higher with methylphenidate; titrate more cautiously and watch for sedation and bradycardia

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Administration

- Once daily at bedtime, with or without food
- Insert the press-in bottle adapter before first use and leave it in place
- **Shake gently up and down at least 10 seconds before every dose;** vigorous shaking foams it and spoils the draw
- Measure only with the supplied oral dispenser, never a spoon
- Supplied in 30 mL, 60 mL and 120 mL bottles
- **Discard** 30 days after opening a 30 mL or 60 mL bottle, 60 days after opening a 120 mL bottle. Store at room temperature, protected from light
- **Missed dose:** skip it; never exceed the prescribed daily total
- **Switching:** stop the other product and titrate from 0.1 mg; never convert mg-for-mg from ER tablets or IR clonidine
- Do not stop abruptly; see Discontinuation & Taper

Side Effects

- **Common** (at least 5% and twice placebo, from the ER tablet trials this label cites):
  - Somnolence, fatigue, irritability, nightmare, insomnia, constipation, dry mouth
  - Somnolence 38% at 0.2 mg/day and 31% at 0.4 mg/day, vs 4% placebo
  - As adjunct: somnolence 19% vs 7%, plus fatigue, decreased appetite, dizziness
- **Serious:**
  - Rebound hypertension on abrupt discontinuation; this label adds that a vomiting illness causing missed doses raises that risk
  - Dose-related hypotension and bradycardia; hold or reduce and recheck
  - 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 generalised rash, urticaria and angioedema; discontinue

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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 morning grogginess at every titration visit and every visit for 3 months
- **Rebound hypertension risk:** at every refill confirm no missed doses or supply gap, and ask about recent gastroenteritis
- **Dosing technique:** at first follow-up have the caregiver demonstrate shaking and drawing the dose
- **ADHD response:** rated scale at 5 to 8 weeks, matching the bridged 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
- **Laboratory:** no routine laboratory monitoring required

Discontinuation & Taper

- **Never stop abruptly.** Reduce by no more than 0.1 mg (1 mL) every 3 to 7 days; from 0.4 mg 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
- **A vomiting illness is de facto abrupt discontinuation,** named in this label for children; families should call, and recheck blood pressure afterwards
- Measure blood pressure and heart rate at each taper step and after the last dose
- **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, miscarriage or adverse outcomes. Animal resorptions at 10x (rat) and 5x (mouse) the maximum human dose; 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 findings suggest impaired fertility in both sexes

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

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Counseling Points

- **Counsel the family on:**
  - Shaking gently 10 seconds before every dose, and using only the supplied dispenser; an unshaken bottle underdoses early and overdoses late
  - Writing the opening date on the bottle, because it is discarded at 30 or 60 days whether or not it is empty
  - The bedtime-only schedule; this is not the twice-daily tablet and the dose does not carry across
  - Sleepiness early being expected while the ADHD benefit takes weeks; watch for morning grogginess
  - Never stopping on their own; name rebound high blood pressure in those words, and never doubling a missed dose
  - Calling during any stomach bug that stops the medicine going down
  - Avoiding alcohol in adolescents, for sedation and because alcohol can speed release
- **Advise them to call for:**
  - Fainting, or dizziness on standing that does not settle
  - A pulse that feels very slow or irregular
  - Morning sleepiness affecting school, or a child hard to wake
  - Severe headache with blurred vision, especially after missed doses
  - New hives, facial or lip swelling, or a widespread rash
  - Any vomiting illness that stops the medicine going down

References

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Revision #12
Created 2025-02-06 19:10:21 UTC by Josh LeJeune NP
Updated 2026-08-20 06:38:23 UTC by Josh LeJeune NP