

New Formulation – Clonidine Extended-Release Oral Suspension
(Onyda XR[®] Tris Pharma, Inc.)
FDA Approved May 2024

Indication: Clonidine extended release (ER) oral suspension is indicated for the treatment of ADHD in pediatric patients aged 6 years and older, either as monotherapy or as an adjunctive therapy alongside CNS stimulant medications.

Mechanism: Clonidine stimulates alpha2-adrenergic receptors in the brain but is not classified as a CNS stimulant. The exact mechanism of action in the treatment of ADHD remains unknown.

Dosage & Administration

Dosage	<ul style="list-style-type: none"> ▪ Initial dose - 0.1 mg once daily at bedtime. Max dose: 0.4 mg QHS ▪ Do not substitute Onyda XR[®] for other clonidine products on a mg-per-mg basis (different PK profiles)
Administration	<ul style="list-style-type: none"> ▪ Administer with or without food ▪ Use the provided dosing dispenser & bottle adapter. Ensure the adapter is securely inserted before first use & remains in place ▪ Shake gently in a smooth up and down motion (to avoid foaming) for at least 10 seconds before each use ▪ Discard any unused suspension after 60 days of opening the bottle
How Supplied	ER oral suspension: 0.1 mg clonidine HCl per mL
Missed dose	Skip the dose and take the next dose as scheduled
Tapering & Discontinuation	Dosage may be increased by 0.1 mg a day at weekly intervals. When discontinuing, taper the dose by no more than 0.1 mg every 3 to 7 days to prevent rebound hypertension
Switching from other clonidine products	Discontinue the previous treatment and titrate with Onyda [®] using the titration schedule

Incidence ≥5% & at least twice that of placebo as monotherapy	Somnolence, fatigue, irritability, nightmare, insomnia, constipation, dry mouth
Incidence ≥5% & at least twice that of placebo as adjunct to psychostimulant	Somnolence, fatigue, decreased appetite, dizziness

Contraindications, Warnings & Precautions

- Hypotension/bradycardia
- Somnolence/Sedation
- Cardiac Conduction Abnormalities

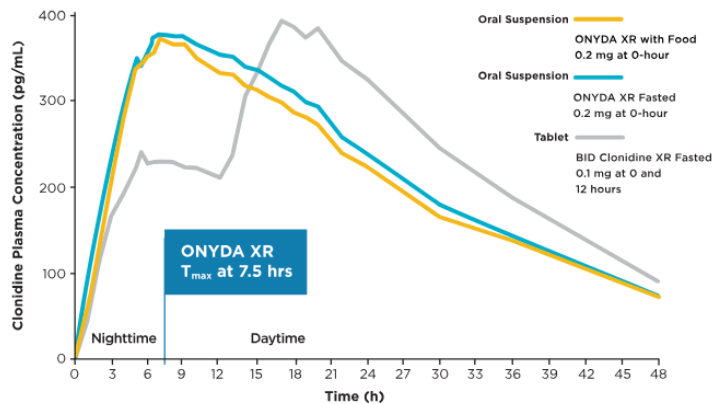
Pharmacokinetics*

Relative Bioavailability	96.1% relative to an equal dose of clonidine ER tabs
Half-life elimination	12–16 hrs (up to 41 hrs in severe renal impairment)

Metabolism	~50% metabolized in the liver
T_{max}	7.5 hrs (4-17 hours)
C_{max}	95.6% of clonidine ER tabs (0.1 mg BID)
Excretion	40–60% excreted unchanged in urine within 24 hrs

*Following a single 0.2 mg Onyda XR dose in 20 fasting adults (crossover study)

Mean clonidine concentration-time profiles after single dose administration of ONYDA XR vs twice-a-day clonidine hydrochloride extended-release tablets (clonidine XR)¹



Role in therapy

- Onyda XR is the first liquid ER non-stimulant approved for ADHD treatment in children aged 6 and older.
- Provides a new formulation of clonidine, a well-established non-stimulant therapy, as an alternative for patients intolerant to stimulants or those with an inadequate response
- Simplifies administration with its orange-flavored liquid form and once-nightly dosing, addressing symptoms throughout the day.
- The safety and efficacy of Onyda XR for treating ADHD in pediatric patients aged 6 and older are supported by well controlled studies of clonidine HCl ER tablets.
- Benefits families with busy mornings, particularly children who face morning challenges.
- Provides an easy to take option for patients who struggle with swallowing pills.
- Reduces stimulant related side effects when used in combination therapy.
- Efficacy is unaffected by food or metabolic variations.
- Jornay PM, a methylphenidate delayed-release/extended-release capsule, and Onyda XR are both indicated for the treatment of ADHD in patients aged 6 and older. While both are designed for nighttime dosing, Jornay PM is a stimulant that provides symptom control starting in the early morning and lasting throughout the day.
- Unclear if Onyda ER has any benefits compared to other medications with demonstrated efficacy.
- Gradual dose titration (0.1 mg per day weekly) may be slow for patients requiring faster dose adjustments.
- Unclear comparative advantage over other clonidine formulations, further head-to-head studies are needed.

Comparative Cost

Drug	Formulation	Daily Dose	Monthly Cost*
Clonidine ER	0.1mg tablet	0.1mg BID	\$20 - \$176
Onyda ER	0.1mg/ml suspension	0.2mg QHS	\$480

*Wholesale Acquisition Cost as of 12/6/2024

Formulary Recommendation

Add to BHRS with Prior Authorization Criteria:

Diagnosis- FDA approved Indications

Required Documentation—Tried and failed Clonidine ER tablets or unable to swallow oral tablets

Quantity Limit: 120ml/30DS

Age Limit: 6 years of age and older.