

FDA approves first liquid, nonstimulant ADHD treatment

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The U.S. Food and Drug Administration has approved Tris Pharma's



once-daily Onyda XR (clonidine hydrochloride) as the first liquid, nonstimulant treatment for attention-deficit/hyperactivity disorder (ADHD).

The once-a-day, extended-release, oral suspension treatment is a centrally acting alpha2-adrenergic agonist. It has nighttime dosing for the treatment of ADHD as a monotherapy or as an adjunctive therapy to approved central nervous system stimulant medications in pediatric patients ≥6 years.

Onyda XR is contraindicated in patients with a history of a hypersensitivity reaction to clonidine. As monotherapy, the most common adverse reactions (incidence ≥5 percent and twice the rate of placebo) include somnolence, fatigue, irritability, nightmare, insomnia, constipation, and dry mouth. For adjunct therapy, the most common adverse reactions (incidence ≥5 percent and twice the rate of placebo) include somnolence, fatigue, decreased appetite, and dizziness.

"People with ADHD require a range of therapeutic options that are designed for their individual needs, because not every medication or type of therapy works for every patient," Ann Childress, M.D., president of the Center for Psychiatry and Behavioral Medicine in Las Vegas, said in a statement.

"The approval of Onyda XR, the only liquid nonstimulant ADHD medication, with nighttime dosing that shifts the release profile, is a convenient option for patients needing better ADHD control."

More information: More Information

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