INDICATION

ONYDA XR is a centrally acting alpha2-adrenergic agonist indicated for the treatment of attention deficit hyperactivity disorder (ADHD) as monotherapy or as adjunctive therapy to central nervous system (CNS) stimulant medications in pediatric patients 6 years of age and older.

IMPORTANT SAFETY INFORMATION

Contraindications:

- ONYDA is contraindicated in patients with history of a hypersensitivity reaction to clonidine.

Warnings & Precautions

- **Hypotension/Bradycardia**: Treatment with ONYDA XR can cause dose-related decreases in blood pressure and heart rate. Titrate slowly and monitor vital signs frequently in patients at risk for hypotension, heart block, bradycardia, syncope, cardiovascular disease, vascular disease, cerebrovascular disease, or chronic renal failure. In patients who have a history of syncope or may have a condition that predisposes them to syncope, such as hypotension, orthostatic hypotension, bradycardia, or dehydration, advise patients to avoid becoming dehydrated or overheated.
- **Somnolence/Sedation**: Somnolence and sedation were commonly reported adverse reactions in clinical studies with clonidine hydrochloride extended-release tablets. Caution patients against operating heavy equipment or driving until they know how they respond to treatment with ONYDA XR. Advise patients to avoid use with alcohol.
- **Cardiac Conduction Abnormalities:** The sympatholytic action of clonidine may worsen sinus node dysfunction and atrioventricular (AV) block, especially in patients taking other sympatholytic drugs. There have been post-marketing reports of patients with conduction abnormalities and/or taking other sympatholytic drugs who developed severe bradycardia requiring intravenous (IV) atropine, IV isoproterenol, and temporary cardiac pacing while taking clonidine. Titrate ONYDA XR slowly and monitor vital signs frequently in patients with cardiac conduction abnormalities or patients concomitantly treated with other sympatholytic drugs.

Adverse Reactions:

- Most common adverse reactions (incidence at least 5% and twice the rate of placebo) as monotherapy in ADHD: somnolence, fatigue, irritability, nightmare, insomnia, constipation, dry mouth.
- Most common adverse reactions (incidence at least 5% and twice the rate of placebo) as adjunct therapy to psychostimulant in ADHD: somnolence, fatigue, decreased appetite, dizziness.

Drug Interactions:

- CNS Depressants: Clonidine may potentiate the CNS-depressive effects of alcohol, barbiturates, or other sedating drugs. Avoid concomitant use of CNS depressants with ONYDA XR.

- Tricyclic Antidepressants: Concomitant use of tricyclic antidepressants with clonidine can increase blood pressure and may counteract the hypotensive effects of clonidine. Monitor blood pressure and adjust dosage of ONYDA XR as needed.
- Drugs Known to Affect Sinus Node Function or AV Nodal Conduction: Avoid use of ONYDA XR with agents known to affect sinus node function or AV nodal conduction (e.g., digitalis, calcium channel blockers and beta-blockers) due to a potential for additive effects such as bradycardia and AV block.
- Antihypertensive drugs: Concomitant use of antihypertensive drugs with clonidine potentiates the hypotensive effects of clonidine. Monitor blood pressure and heart rate and adjust dosage of ONYDA XR accordingly in patients treated concomitantly with antihypertensives.

Use in specific population:

- Use in patients with renal Impairment: The impact of renal impairment on the pharmacokinetics of clonidine in pediatric patients has not been assessed. The dosage of ONYDA XR must be adjusted according to the degree of impairment, and patients should be carefully monitored.
- Use during pregnancy: Prolonged experience with clonidine in pregnant women over several decades, based on published literature, including controlled trials, a retrospective cohort study and case reports, have not identified a drug associated risk of major birth defects, miscarriage, and adverse maternal or fetal outcomes.

  To monitor pregnancy outcomes in women exposed to ADHD medications, including ONYDA XR, during pregnancy, healthcare providers are encouraged to register patients by calling the National Pregnancy Registry for Psychiatric Medications at 1-866-961-2388 or visiting online at https://womensmentalhealth.org/adhd-medications/.
- Use during lactation: The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ONYDA XR and any potential adverse effects on the breastfed child from ONYDA XR or from the underlying maternal condition. Monitor breastfeeding infants exposed to ONYDA XR through breast milk for symptoms of hypotension and/or bradycardia such as sedation, lethargy, tachypnea, and poor feeding.

To report SUSPECTED ADVERSE REACTIONS, contact Tris Pharma, Inc. at 1-732-940-0358 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Please see ONYDA PI for full prescribing information