



#### **APPROVED USE**

ONYDA XR (clonidine HCl) is a prescription medicine used for the treatment of attention deficit hyperactivity disorder (ADHD) alone or with certain other ADHD medicines in children 6 years of age and older.

It is not known if ONYDA XR is safe and effective in children under 6 years of age.





#### **About ADHD**

Attention Deficit Hyperactivity Disorder (ADHD) is one of the **most common childhood neurodevelopmental disorders** in the U.S., affecting as many as:

**11.4%** of children aged 3-17

#### **ADHD** treatment

Medications can be effective for treating ADHD symptoms and are usually well tolerated - but treatment of ADHD isn't the same for everyone. Some people may not respond to a specific medication, for example, or have side effects that are hard to manage.

If you and your doctor are exploring treatments for your child, ONYDA XR is a unique option.

The only non-stimulant for ADHD in a liquid formulation, ONYDA XR is dosed at night for daytime control of ADHD symptoms.

It's that simple. Read this brochure to learn more!

## Meet ONYDA XR!

ONYDA XR is a unique extended-release form of clonidine, a non-stimulant that has been used to treat ADHD for many years.



#### Nightly dosing

ONYDA XR is dosed **once-nightly** for ADHD symptom control the following day.



#### **Continuous release**

With a **single nighttime dose**, ONYDA XR provides extended-release through the day.



#### **Liquid formulation**

ONYDA XR is an orange flavored oral suspension — the **only liquid non-stimulant for ADHD.** 

#### IMPORTANT SAFETY INFORMATION

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# A nighttime non-stimulant

# for ADHD control during the day







### Easy to take liquid medicine



- · ONYDA XR is an orange-flavored liquid
- Follow the schedule provided by your doctor and administer using the provided dispenser
- Your healthcare provider will identify your child's dose by adjusting it up or down in small amounts based on your child's response to treatment

Do not suddenly stop ONYDA XR without first talking to your healthcare provider. Your child may need to gradually reduce dosage to avoid a rebound of high blood pressure.

## **Powerful symptom control that lasts**

- Lasting improvement in attention and behavior when used alone
- Significantly improves ADHD symptom control when added to stimulant therapy

# **Consistent medication delivery**

- Continuous, smooth release of clonidine through the day
- · Release not affected by food your child eats
- Release <u>not</u> affected by the metabolism of clonidine

#### IMPORTANT SAFETY INFORMATION (cont'd)

#### Who should not take ONYDA XR?

Do not take ONYDA XR if you are allergic to clonidine.

#### **ONYDA XR can cause serious side effects including:**

- Allergic reactions: You may develop an allergic reaction to ONYDA XR if you had an allergic reaction to clonidine taken through your skin in a patch. Stop taking ONYDA XR and call your healthcare provider right away or go to the nearest emergency room if you develop any signs or symptoms of an allergic reaction, including:
  - skin rash
  - hives
  - swelling of the eyes, face, lips, or tongue

# Once before bed.





#### How to administer ONYDA XR



- Take ONYDA XR exactly as prescribed
- ONYDA XR should be taken by mouth once daily before bed
- ONYDA XR can be taken with or without food
- ONYDA XR comes with an oral dosing dispenser to help you measure the correct amount of medication
- Gently shake the bottle up and down for 10 seconds prior to each use
- Keep ONYDA XR at room temperature
- Do not stop taking ONYDA XR without speaking to your doctor. ONYDA XR should not be discontinued abruptly

Please click to see the Full Instructions for Use.

#### **IMPORTANT SAFETY INFORMATION (cont'd)**

ONYDA XR can cause serious side effects including: (cont'd)

- **Decreased blood pressure and heart rate.** ONYDA XR can decrease your blood pressure and heart rate, which can increase your chance of passing out (syncope). If you have a history of passing out or have other medical problems as mentioned above, your risk is higher. Your healthcare provider should check your heart rate and blood pressure before starting treatment and regularly during treatment with ONYDA XR. **Do not** become dehydrated or too hot (overheated) to decrease your chance of passing out during treatment with ONYDA XR.
- Before taking ONYDA XR, tell your healthcare provider about all of your medical conditions, including if you: have kidney problems, have low or high blood pressure, have heart problems, including slow heart rate or other heart rhythm problems, had a stroke or have stroke symptoms.



#### **IMPORTANT SAFETY INFORMATION (cont'd)**

ONYDA XR can cause serious side effects including: (cont'd)

- Sleepiness and tiredness that could cause slow reaction times (sedation and somnolence). Do not drive, operate heavy machinery, or do other dangerous activities until you know how ONYDA XR affects you because ONYDA XR can cause sleepiness and tiredness that could cause slow reaction times. Do not drink alcohol or take other medicines that make you sleepy or dizzy during treatment with ONYDA XR until you talk with your healthcare provider.
- Rebound high blood pressure (hypertension). Suddenly stopping ONYDA XR can cause high blood pressure to return if you have a history of high blood pressure. Suddenly stopping ONYDA XR may also cause withdrawal symptoms including headache, increased heart rate, nausea, flushing or warm feeling, lightheadedness, tightness in your chest and nervousness or anxiety. Do not suddenly stop ONYDA XR treatment without first talking to your healthcare provider. Tell your healthcare provider if you have been vomiting and cannot take ONYDA XR, you may be at risk for rebound hypertension.

#### The most common side effects of ONYDA XR when used alone include:

- falling asleep or sleepiness and tiredness that could cause slow reaction times
- irritabilitydry mouthconstipation
- nightmaretrouble sleeping

#### The most common side effects of ONYDA XR when used with other ADHD medicines include:

- falling asleep or sleepiness and tiredness that could cause slow reaction times
- decreased appetite
  dizziness

ONYDA XR may cause fertility problems in females and males, which may affect your ability to have a child. Talk to your healthcare provider if this is a concern for you.











# When mornings are a problem

For children who have difficulties before their medication starts working in the morning, the convenience of nighttime dosing may result in a better daytime routine.

## An alternative to swallowing pills

The liquid formulation of ONYDA XR is easy to take before bed with or without food.

For children who have difficulty swallowing tablets, ONYDA XR is easy to administer and doesn't need to be mixed or sprinkled in food.

#### **IMPORTANT SAFETY INFORMATION (cont'd)**

These are not all of the possible side effects of ONYDA XR. Call your doctor for medical advice about side effects.

ONYDA XR and certain other medicines may affect each other causing serious side effects. **Especially tell your healthcare provider if you take:** 

- anti-depression medicines
- heart or blood pressure medicines
- other medicines for ADHD
- other medicines that contain clonidine
- medicines that cause sleepiness (sedation)

Ask your healthcare provider or pharmacist if you are not sure if your medicine is listed above.

Know the medicines that you take. Keep a list of your medicines with you to show your healthcare provider and pharmacist when you get a new medicine.





# Patients pay as little as \$25 on each prescription\*

Visit <u>ONYDA.com</u> for more information, including Terms and Conditions.

\*See full Terms and Conditions at ONYDA.com/savings-and-support

#### IMPORTANT SAFETY INFORMATION (cont'd)

Before taking ONYDA XR, tell your healthcare provider, if you:

- are pregnant or plan to become pregnant. It is not known if ONYDA XR will harm the unborn baby.
  - There is a pregnancy registry for females who are exposed to ADHD medications, including ONYDA XR, during pregnancy. The purpose of the registry is to collect information about the health of females exposed to ONYDA XR and their baby. If you become pregnant during treatment with ONYDA XR, talk to your healthcare provider about registering with the National Pregnancy Registry of ADHD Medications at 1-866-961-2388 or visit online at <a href="https://womensmentalhealth.org/adhdmedications/">https://womensmentalhealth.org/adhdmedications/</a>.
- are breastfeeding or plan to breastfeed. ONYDA XR passes into the breast milk. Babies who are breastfed during treatment with ONYDA XR may become very sleepy, develop relaxed or floppy muscles, and develop trouble breathing. Call the baby's healthcare provider if the baby is breastfed during treatment with ONYDA XR and develops any of these symptoms. Talk to your healthcare provider about the best way to feed your baby if you take ONYDA XR.

To report side effects, contact Tris Pharma, Inc at 1-732-940-0358 or to the FDA at <a href="www.fda.gov/medwatch">www.fda.gov/medwatch</a>, or call 1-800-FDA-1088.

REFERENCES: 1. ONYDA XR [package insert]. Tris Pharma, Inc., Monmouth Junction, NJ. 2. Northwell Health System. The ADHD Medication Guide. ©Northwell Health, Inc. Published 2011-2015. Accessed August 27, 2025. https://www.adhdmedicationguide.com. 3. Danielson ML, et al. ADHD Prevalence Among U.S. Children and Adolescents in 2022: Diagnosis, Severity, Co-Occurring Disorders, and Treatment. *Journal of Clinical Child & Adolescent Psychology*. 2024 53(3), 343–360. 4. Faraone, S.V., Bellgrove, M.A., Brikell, I. et al. Attention-deficit/hyperactivity disorder. *Nat Rev Dis Primers* 10, 11 (2024). 5. Jain R, Segal S, Kollins SH, Khayrallah M. Clonidine extended-release tablets for pediatric patients with attention-deficit/hyperactivity disorder. *J Am Acad Child Adolesc Psychiatry*. 2011 Feb;50(2):171-9. 6. Kollins SH, Jain R, Brams M, Segal S, Findling RL, Wigal SB, Khayrallah M. Clonidine extended-release tablets as add-on therapy to psychostimulants in children and adolescents with ADHD. *Pediatrics*. 2011 Jun;127(6):e1406-13. 7. Rafla E, Witkovic M, Horng J, Potenziano J, Grieco J. A randomized, open label, multiple-dose, two-way study to evaluate bioavailability of clonidine HCl extended-release oral suspension compared to clonidine HCl extended-release tablets. Poster presented at: Psych Congress; October 29 - November 2, 2024; Boston, MA

Please see Important Safety Information throughout and <u>Full Prescribing Information</u>, including <u>Patient Information</u> and Instructions for Use.

