

**PATIENT INFORMATION**  
**ONYDA™ XR (oh-nee-dah)**  
**(clonidine hydrochloride)**  
**extended-release oral suspension**

**What is ONYDA XR?**

ONYDA XR 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.

**Who should not take ONYDA XR?**

**Do not take ONYDA XR if you** are allergic to clonidine. See the end of this Patient Information for a complete list of ingredients in 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 a history of passing out (syncope)
- have heart problems, including slow heart rate or other heart rhythm problems
- had a stroke or have stroke symptoms
- had an allergic reaction after taking clonidine through your skin in a transdermal system (patch)
- are pregnant or plan to become pregnant. It is not known if ONYDA XR will harm the unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
  - 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 <https://womensmentalhealth.org/adhdmedications/>
- 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.

**Tell your healthcare provider about all of the medicines that you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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.

**How should I take ONYDA XR?**

- Take ONYDA XR 1 time daily at bedtime with or without food.
- Take ONYDA XR exactly as your healthcare provider tells you.
- Your healthcare provider may change your dose of ONYDA XR. Do not change your dose of ONYDA XR without talking to your healthcare provider.
- **If you are taking another clonidine medicine, stop taking it** before you start treatment with ONYDA XR.
- **The dose of ONYDA XR is not the same as other clonidine medicines. Do not** change between ONYDA XR and other clonidine medicines unless your healthcare provider tells you.
- **Do not** stop taking ONYDA XR without talking to your healthcare provider.
- If you miss a dose of ONYDA XR, skip the missed dose and take the next dose at their regular scheduled time. Do not take more ONYDA XR in a 24-hour period than your healthcare provider prescribed for your daily dose.
- Throw away (discard of) any remaining ONYDA XR if you have not used it after 60 days of first opening the bottle.
- **See the detailed Instructions for Use for information on how to take a dose of ONYDA XR.**

If you take too much ONYDA XR, call your healthcare provider or Poison Help line at 1-800-222-1222, or go to the nearest hospital emergency room right away.

### What should I avoid while taking ONYDA XR?

- **Do not** become dehydrated or too hot (overheated) to decrease your chance of passing out during treatment with ONYDA XR.
- **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. Taking ONYDA XR with alcohol or medicines that cause sleepiness or dizziness may make your sleepiness or dizziness worse.

### What are possible side effects of ONYDA XR?

#### ONYDA XR may cause serious side effects, including:

- **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 or take other medicines that increase your risk of passing out, 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. See “What should I avoid while taking ONYDA XR?”
- **Sleepiness and tiredness that could cause slow reaction times (sedation and somnolence).** See “What should I avoid while taking ONYDA XR?”
- **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.**
- **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

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

- falling asleep or sleepiness and tiredness that could cause slow reaction times
- irritability
- nightmare
- trouble sleeping
- constipation
- dry mouth

#### 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.

These are not all of the possible side effects of ONYDA XR.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### How should I store ONYDA XR?

- Store ONYDA XR at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect from light and keep ONYDA XR in the original container. Tightly close the child-resistant cap.
- Throw away (discard of) any remaining ONYDA XR if you have not used it after 60 days of first opening the bottle.

### Keep ONYDA XR and all medicines out of the reach of children.

### General information about the safe and effective use of ONYDA XR.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ONYDA XR for a condition for which it was not prescribed. Do not give ONYDA XR to other people, even if they have the same symptoms that you have. It may harm them. You can also ask your pharmacist or healthcare provider for information about ONYDA XR that is written for health professionals.

### What are the ingredients in ONYDA XR?

**Active Ingredient:** clonidine hydrochloride

**Inactive Ingredients:** anhydrous citric acid, edetate disodium, glycerin, modified starch, methylparaben, orange flavor, polyvinyl acetate dispersion 30%, povidone, polysorbate 80, propylparaben, purified water, sucrose, sodium polystyrene sulfonate, triacetin, and xanthan gum

Manufactured by/Distributed by:

**Tris Pharma, Inc.**

Monmouth Junction, NJ 08852

[www.trispharma.com](http://www.trispharma.com)

For more information about ONYDA XR call 1-732-940-0358.

**INSTRUCTIONS FOR USE**  
**ONYDA™ XR (oh-nee-dah)**  
**(clonidine hydrochloride)**  
**extended-release oral suspension**

This Instructions for Use contains information on how to take ONYDA XR.

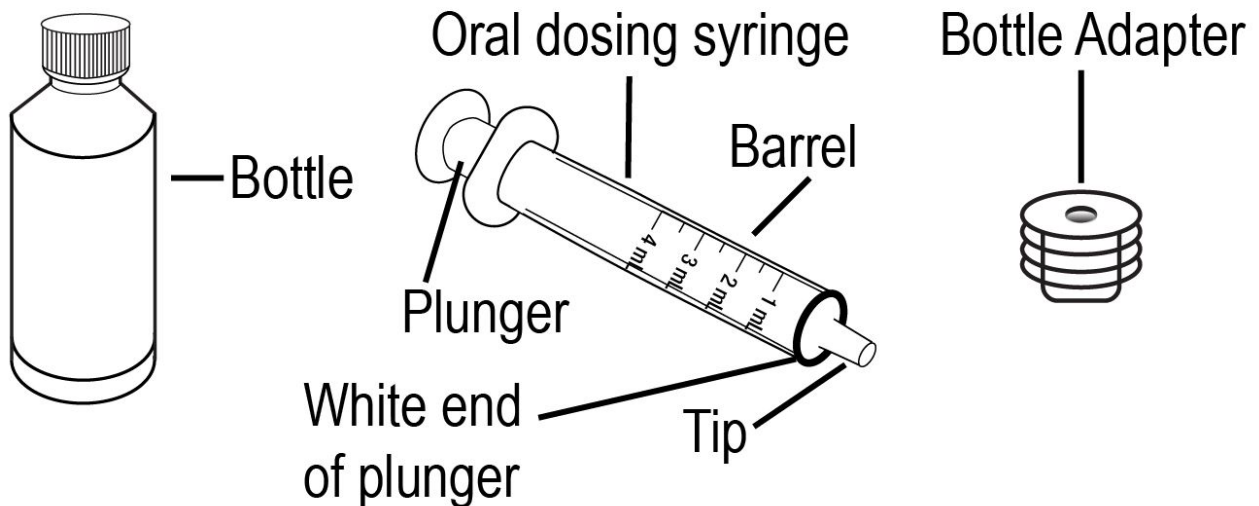
**Important Information You Need to Know Before Taking ONYDA XR:**

- ONYDA XR is for oral use only (taken by mouth).
- Take ONYDA XR with or without food.
- Use only the oral dosing syringe and bottle adapter that come with ONYDA XR to measure and take a dose of ONYDA XR.
- Shake the ONYDA XR bottle gently.
- Check the expiration date (EXP) on the carton label. Do not take ONYDA XR after the expiration date has passed. Call your healthcare provider or pharmacist if your medicine is expired.
- Throw away (discard of) any remaining ONYDA XR if you have not used it after 60 days of first opening the bottle.

**Supplies included in the ONYDA XR carton:**

- 1 bottle of ONYDA XR
- 2 oral dosing syringes
- 2 bottle adapters

Figure A



**Step 1:**

**Preparing to take ONYDA XR:**

- Wash and dry your hands (see Figure B).
- Remove the ONYDA XR bottle, 1 oral dosing syringe, and 1 bottle adapter from the carton.

Tell your pharmacist right away if you are missing any supplies from the carton.

Figure B



**Step 2:**

- Place the ONYDA XR bottle on a flat surface like a table or countertop and remove the child resistant cap by pressing down and turning counterclockwise (see Figure C).

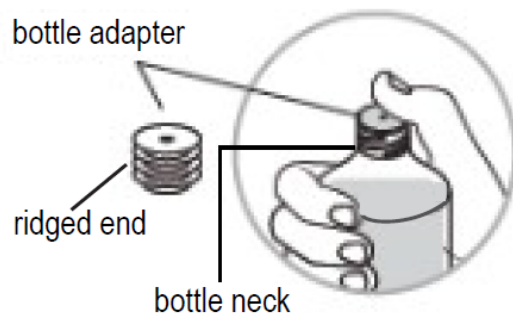
Figure C



**Insert the bottle adapter (first time use only).**

- Hold the bottle firmly and insert the ridged end of the bottle adapter into the neck of the bottle.
- Firmly push the bottle adapter all the way down with your thumb until the top of the adapter is aligned and flat (flush) with the top of the bottle (See Figure D).
- Do not remove the bottle adapter once it has been inserted into the bottle.

Figure D



**Step 3:**

- Put the cap back on the bottle and close it tightly by turning the cap clockwise (see Figure E).
- Shake the bottle gently with a smooth up and down motion to avoid foaming (see Figure F).
- Shake the bottle gently for at least 10 seconds before you take each dose.

Figure E

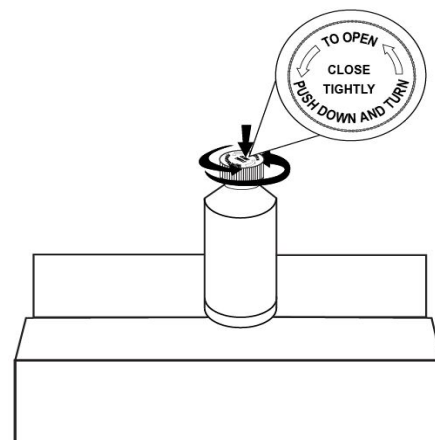


Figure F

**Step 4:**

- Place the ONYDA XR bottle upright on the table or countertop. Open the cap again by pressing down and turn counterclockwise to remove the cap (see Figure G).

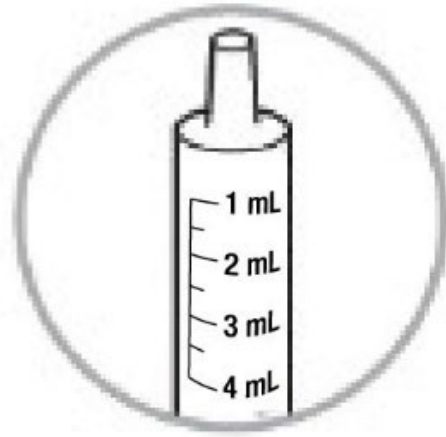
Figure G



**Step 5:**

- Check the ONYDA XR oral dosing syringe to find the right dose in milliliters (mL) that has been prescribed by the healthcare provider (see Figure H).
- Make sure the oral dosing syringe is dry.

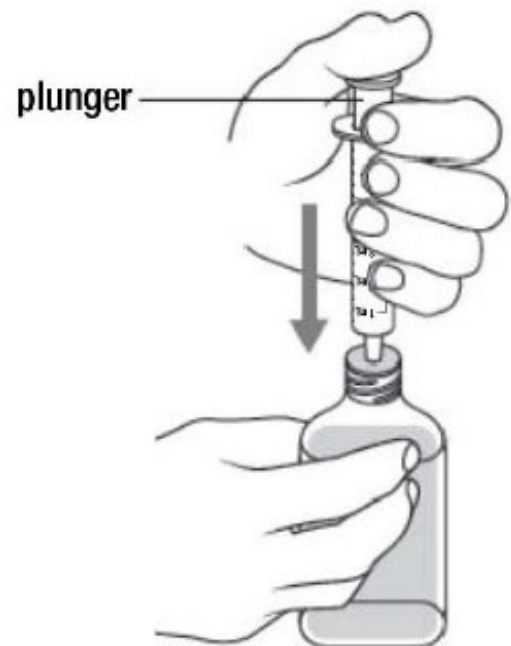
Figure H



**Step 6:**

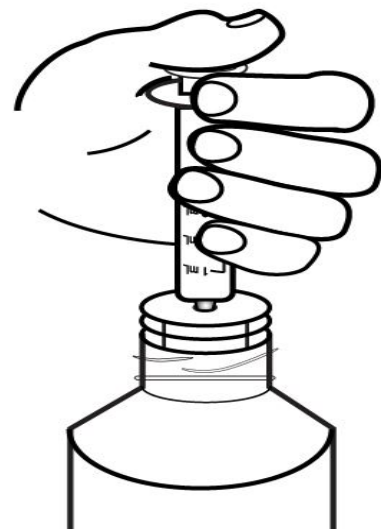
- Insert the tip of the oral dosing syringe through the adapter into the bottle (see Figure I).

Figure I



- Push the plunger all the way down (see Figure J).

Figure J



**Step 7:**

**Measuring the dose of ONYDA XR:**

- With the tip of the oral dosing syringe in place in the adapter, hold the ONYDA XR bottle upside down. Pull the plunger down until the white end of the plunger reaches the number of mL you need for the prescribed dose (see Figure K).
- Push and pull the plunger a few times to make sure that there are no air bubbles.
- Tap the barrel of the oral dosing syringe if needed to get rid of any air bubbles (see Figure L).

Figure K

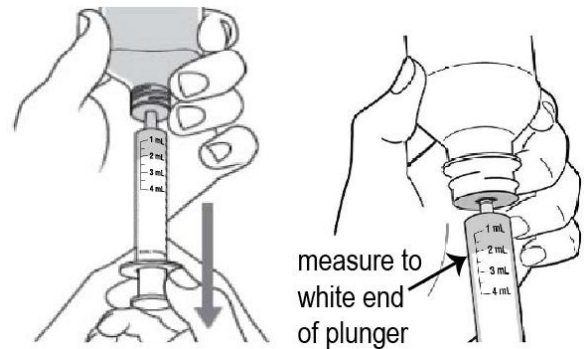
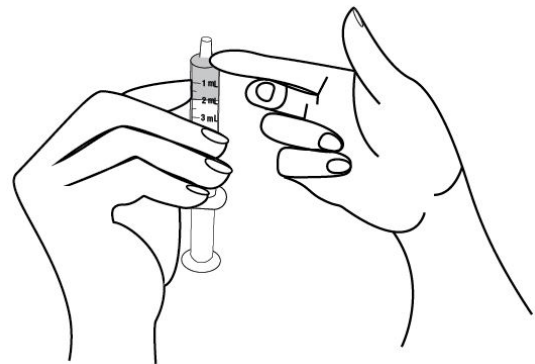


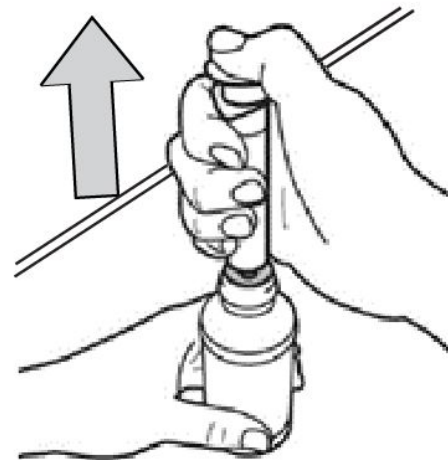
Figure L



**Step 8:**

- Turn the bottle over and place it upright on a table or countertop, then remove the oral dosing syringe from the bottle adapter (see Figure M).

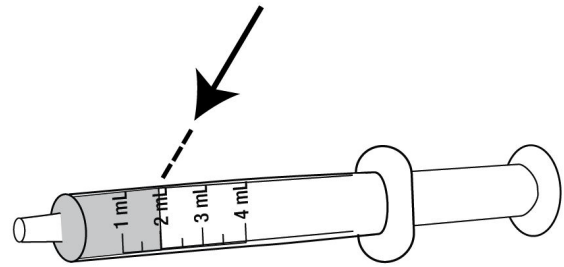
Figure M



**Step 9:**

- Check that the correct dose in mL was pulled up into the oral dosing syringe (see Figure N).
- If the dose is not correct:
  - Insert the oral syringe tip back into the bottle and fully push in the plunger to the bottom of the syringe barrel so that all of the oral suspension flows back into the bottle.
  - Repeat Steps 6 through 8.

Figure N

**Step 10:****Taking the dose of ONYDA XR:**

- The child should be in a seated position before taking ONYDA XR.
- Tilt the head slightly upwards.
- Place the oral dosing syringe into the mouth and point it toward the cheek (see Figure O).
- Close the mouth tightly around the oral dosing syringe and slowly push the plunger all the way down to give the ONYDA XR dose (see Figure P).
- After all the medication has been taken, remove the oral dosing syringe from the mouth.

Figure O



Figure P





**Step 11:****Closing the bottle:**

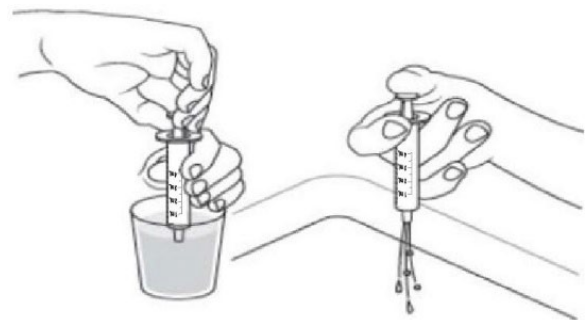
- Put the ONYDA XR cap back on the bottle and close the cap tightly by turning the cap clockwise (see Figure Q).

Figure Q

**Step 12:****Cleaning up:**

- Clean the oral dosing syringe after each use by rinsing with tap water (see Figure R).
- Allow the oral dosing syringe to dry and keep it in a safe place for the next use.
- Wash and dry your hands.

Figure R

**Disposing of ONYDA XR:**

- Throw away any unused or expired ONYDA XR in your household trash.
- Throw away any remaining ONYDA XR if you have not used it 60 days after first opening the bottle.

**Storing ONYDA XR:**

- Store ONYDA XR at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect from light and keep ONYDA XR in the original container. Tightly close the child-resistant cap.

**Keep ONYDA XR and all medicines out of the reach of children.**

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Rev. 00

This Instructions for Use has been approved by the U.S. Food and Drug Administration

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