

MEDICATION GUIDE
RALDESY™ (ral DEH see)
(trazodone hydrochloride)
oral solution

What is the most important information I should know about RALDESY?

RALDESY can cause serious side effects, including:

- **Increased risk of suicidal thoughts or actions.** RALDESY and other antidepressant medicines increase the risk of suicidal thoughts and actions in people 24 years of age and younger, **especially within the first few months of treatment or when the dose is changed. RALDESY is not for use in children.**

- **Depression and other mental illnesses are the most important causes of suicidal thoughts and actions.**

How can I watch for and try to prevent suicidal thoughts and actions?

- Pay close attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings if you develop suicidal thoughts or actions. This is very important when an antidepressant medicine is started or when the dose is changed.
- Call your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts or feelings, or if you develop suicidal thoughts or actions.
- Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

Call a healthcare provider right away if you have any of the following symptoms, especially if they are new, worse, or worry you:

- attempts to commit suicide
- thoughts about suicide or dying
- feeling agitated, restless, angry, or irritable
- other unusual changes in behavior and mood
- acting on dangerous impulses
- new or worse depression
- trouble sleeping
- acting aggressive or violent
- a new or worse anxiety or panic attacks
- an increase in activity or talking more than what is normal for you

See **“What are the possible side effects of RALDESY?”** for more information about side effects.

What is RALDESY?

RALDESY is a prescription medicine used in adults to treat major depressive disorder (MDD). It is not known if RALDESY is safe and effective for use in children.

Who should not take RALDESY?

Do not take RALDESY if you:

- are taking, or have stopped taking within the last 14 days, a medicine called Monoamine Oxidase Inhibitor (MAOI), including the antibiotic linezolid and intravenous methylene blue

Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid or intravenous blue.

Do not start taking an MAOI for at least 14 days after you stop treatment with RALDESY.

Before taking RALDESY tell your healthcare provider about all of your medical conditions, including if you:

- have or have a family history of heart problems, including fast or slow heartbeat, or changes in the electrical activity of your heart (QT prolongation)
- have ever had a heart attack
- have or have had bleeding problems
- are male and have conditions that may cause a prolonged or painful erection (priapism) such as sickle cell anemia, multiple myeloma, leukemia, or a deformed penis
- have or have a family history of bipolar disorder, mania, or hypomania
- have high pressure in the eye (glaucoma)
- have low sodium levels in your blood
- are pregnant or plan to become pregnant. It is not known if RALDESY will harm your unborn baby. Talk to your healthcare provider about the risks to you or your unborn baby if you take RALDESY during pregnancy.
 - Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with RALDESY.
 - There is a pregnancy registry for females who are exposed to RALDESY during pregnancy. The purpose of this registry is to collect information about the health of females exposed to RALDESY and their baby. If you become pregnant during treatment with RALDESY, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants. You can register by calling 1-866-961-2388 or visiting online at

<https://womensmentalhealth.org/research/pregnancyregistry/antidepressants/>.

- are breastfeeding or plan to breastfeed. RALDESY passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with RALDESY.

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

RALDESY and some other medicines may affect each other causing serious side effects. RALDESY may affect the way other medicines work and other medicines may affect the way RALDESY works.

Especially tell your healthcare provider if you take:

- MAOIs
- medicines used to treat migraine headache called triptans
- medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclic antidepressants, lithium, selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), buspirone, or antipsychotics
- tramadol, fentanyl, or other opioids
- over-the-counter supplements such as tryptophan or St. John's Wort
- medicines used to treat high blood pressure
- medicines used to treat irregular heartbeats
- medicines that affect blood clotting such as aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), warfarin or other blood thinners
- digoxin
- medicines used to treat seizures or convulsions
- diuretics

Ask your healthcare provider if you are not sure if you are taking any of these medicines. Your healthcare provider can tell you if it is safe to take RALDESY with your other medicines.

Do not start or stop any other medicines during treatment with RALDESY without talking to your healthcare provider first. Stopping RALDESY suddenly may cause you to have serious side effects. See, **“What are the possible side effects of RALDESY?”**

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

How should I take RALDESY?

See the detailed Instructions for Use that comes with RALDESY for information on how to take RALDESY oral solution.

- Take RALDESY exactly as your healthcare provider tells you. Your healthcare provider may need to change your dose of RALDESY until it is the right dose for you.
- If you feel sleepy after taking RALDESY, talk to your healthcare provider. Your healthcare provider may change your dose or the time of day you take your RALDESY.
- Take RALDESY after a meal or light snack.
- Do not stop taking RALDESY without talking to your healthcare provider.
- If you take too much RALDESY, call your healthcare provider, your Poison Help Line at 1-800-222-1222, or go to the nearest hospital emergency room right away.

What should I avoid while taking RALDESY?

- **Do not** drive, operate heavy machinery, or do other dangerous activities until you know how RALDESY affects you. RALDESY can cause sleepiness or may affect your ability to make decisions, think clearly, or react quickly.
- **Do not** drink alcohol or take other medicines that make you sleepy or dizzy during treatment with RALDESY until you talk with your healthcare provider. RALDESY may make your sleepiness or dizziness worse if you drink alcohol or take other medicines that cause sleepiness or dizziness.

What are the possible side effects of RALDESY?

RALDESY can cause serious side effects, including:

- See **“What is the most important information I should know about RALDESY?”**

Serotonin syndrome. A potentially life-threatening problem called serotonin syndrome can happen when you take RALDESY with certain other medicines. See **“Who should not take RALDESY?”** **Call your healthcare provider or go to the nearest hospital emergency room right away** if you have any of the following signs and symptoms of serotonin syndrome:

- | | |
|---|---|
| ○ agitation | ○ flushing |
| ○ seeing or hearing things that are not real (hallucinations) | ○ high body temperature (hyperthermia) |
| ○ confusion | ○ shaking (tremors), stiff muscles, or muscle twitching |

- coma
- fast heartbeat
- changes in blood pressure
- sweating
- loss of coordination
- seizures
- nausea, vomiting, diarrhea
- dizziness

- **Changes in the electrical activity of your heart (QT prolongation).** Call your healthcare provider right away if you have any of the following symptoms: abnormal heartbeats, dizziness, feel lightheaded or faint.
 - **Low blood pressure and fainting.** Low blood pressure can happen when you change positions from sitting to standing or laying down. You may feel dizzy, lightheaded, or faint.
 - **Increased risk of bleeding.** Taking RALDESY with aspirin, non-steroidal anti-inflammatory drugs (NSAIDs), warfarin, or blood thinners may add to this risk. Tell your healthcare provider right away about any unusual bleeding or bruising.
 - **Painful erection lasting for more than 6 hours (priapism).** If you have an erection that lasts more than 4 hours, get medical help right away.
 - **Manic episodes.** Manic episodes may happen in people with bipolar disorder who take RALDESY. Symptoms may include:
 - greatly increased energy
 - racing thoughts
 - unusually grand ideas
 - talking more or faster than usual
 - severe problems sleeping
 - reckless behavior
 - excessive happiness or irritability
 - **Discontinuation syndrome.** Suddenly stopping RALDESY may cause you to have serious side effects. Your healthcare provider may want to decrease your dose slowly. Symptoms may include:
 - nausea
 - sweating
 - changes in your mood
 - irritability and agitation
 - dizziness
 - electric shock feeling (paresthesia)
 - tremor
 - anxiety
 - confusion
 - headache
 - tiredness
 - problems sleeping
 - hypomania
 - ringing in the ears (tinnitus)
 - seizures
 - **Eye problems (angle-closure glaucoma).** RALDESY can cause a type of eye problem called angle-closure glaucoma in people with certain eye conditions. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are. Call your healthcare provider if you have changes in your vision, eye pain, or swelling or redness in or around the eye.
 - **Low sodium in your blood (hyponatremia).** Low sodium levels in your blood that may be serious and may cause death, can happen during treatment with RALDESY. Elderly people and people who take certain medicines may be at greater risk for this. Signs and symptoms may include:
 - headache
 - difficulty concentrating
 - memory changes
 - confusion
 - weakness and unsteadiness on your feet, which can lead to falls
- In more severe or sudden cases, signs and symptoms include:**
- seeing or hearing things that are not real (hallucinations)
 - fainting
 - seizures
 - coma
 - stopping breathing (respiratory arrest)

The most common side effects of RALDESY include:

- swelling
- blurred vision
- fainting
- sleepiness
- tiredness
- diarrhea
- stuffy nose
- weight loss

These are not all of the possible side effects of RALDESY.

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 RALDESY?

- Store RALDESY at room temperature between 68°F to 77°F (20°C to 25°C).
- RALDESY comes in a bottle with a child-resistant cap.
- Keep RALDESY out of the light.
- Throw away (discard) RALDESY 30 days after first opening the bottle.

- Safely throw away medicine that is out of date or no longer needed.

Keep RALDESY and all medicines out of the reach of children

General information about the safe and effective use of RALDESY.

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

What are the ingredients in RALDESY?

Active ingredient: trazodone hydrochloride, USP

Inactive ingredients: disodium edetate, glycerin, ortho phosphoric acid, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, and sucralose.

Manufactured for and distributed by:

Validus Pharmaceuticals LLC
Parsippany, NJ 07054

For more information, go to www.RALDESY.com or call **Validus Pharmaceuticals LLC at 1-866-982-5438**.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

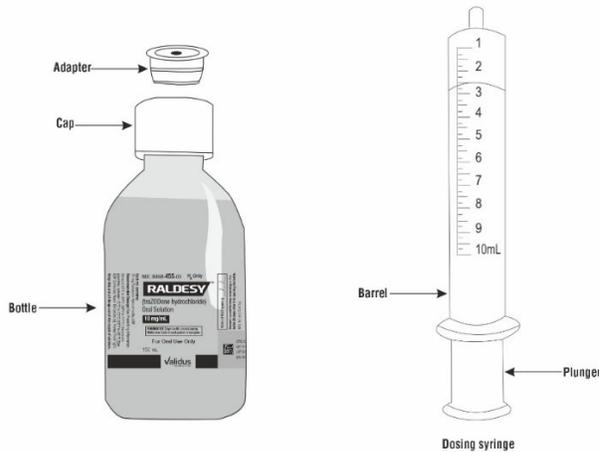
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INSTRUCTIONS FOR USE
RALDESY™ (ral DEH see)
(trazodone hydrochloride)
oral solution

This Instructions for Use contains information on how to take RALDESY.

Read this Instructions for Use before you start taking RALDESY for the first time and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

Supplies needed to take RALDESY



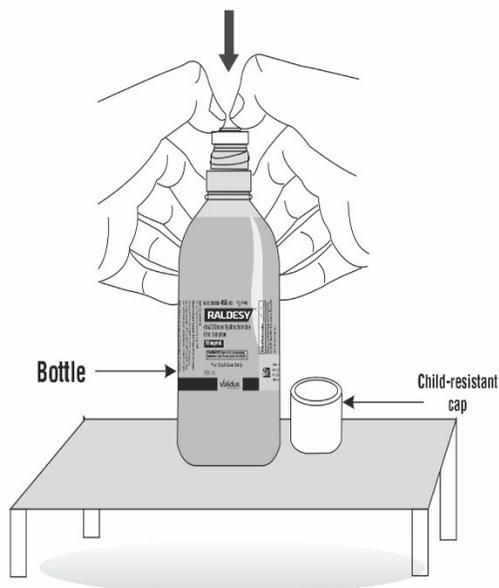
Each carton of RALDESY contains:

- 1 bottle of RALDESY oral solution
- 1 plastic adapter
- One 10 mL oral dosing syringe

Important Information You Need to Know Before Taking RALDESY

- For oral use only (taken by mouth).
- Use the plastic adapter and oral dosing syringe that comes in the carton. If you did not receive the plastic adapter and oral dosing syringe, contact your pharmacist.
- Ask your pharmacist how to measure your prescribed doses.
- Take RALDESY exactly as prescribed by your healthcare provider. **Do not** stop taking RALDESY without first talking to your healthcare provider.
- Take RALDESY after a meal or light snack.
- Check the expiration date on the bottle. If you have not opened the RALDESY bottle, **do not** use RALDESY if the expiration date on the bottle has passed. Contact your healthcare provider or pharmacist.
- **Do not** use RALDESY 30 days after first opening the bottle.

Preparing the RALDESY bottle



Step 1. Remove the child-resistant cap by pushing it **firmly** down and turning it counterclockwise (to the left), as shown on the top of the child-resistant cap.

Note: Save the child-resistant cap so you can close the bottle after each use.

Step 2. Hold the open bottle upright on a table and push the ribbed end of the plastic adapter firmly into the neck of the bottle as far as you can.

Step 3. Put the child-resistant cap back on the bottle to make sure the plastic adapter has been fully inserted into the neck of the bottle.

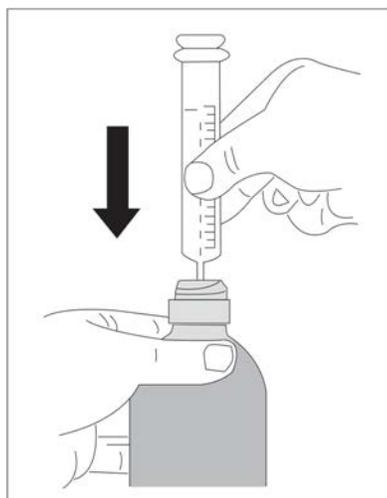
Note: You may not be able to push the plastic adapter all the way down, but it will be forced into the bottle when you put the child-resistant cap back on.

Now the bottle is ready to use with the oral dosing syringe.

Do not remove the adapter. The plastic adapter must always stay in the bottle. The child-resistant cap should seal the bottle in between use.

Write the date of first opening the RALDESY bottle.

Preparing the dose of RALDESY oral solution

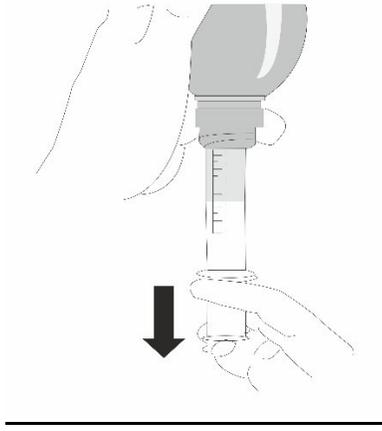


Step 4. Push down and turn the child-resistant cap to the left to open the bottle.

Note: Always replace the cap after use.

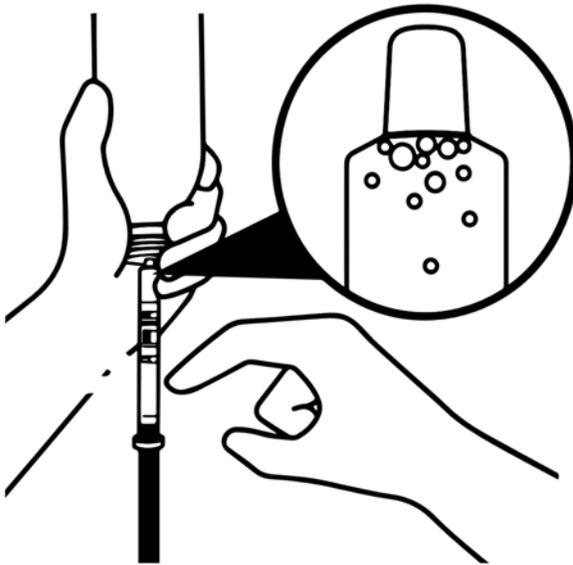
Step 5. Check that the plunger is all the way down inside the barrel of the oral dosing syringe.

Step 6. Keep the bottle upright and push the tip of the oral dosing syringe **firmly** into the plastic adapter.



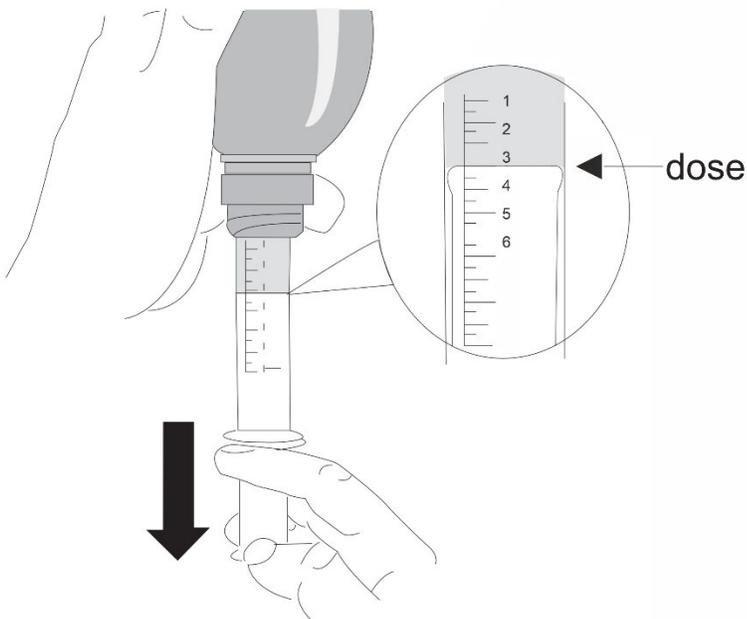
Step 7. Hold the syringe in place and carefully turn the bottle upside down.

Step 8. Slowly pull down the plunger to fill the oral dosing syringe slightly past your prescribed dose line to help remove any air bubbles.



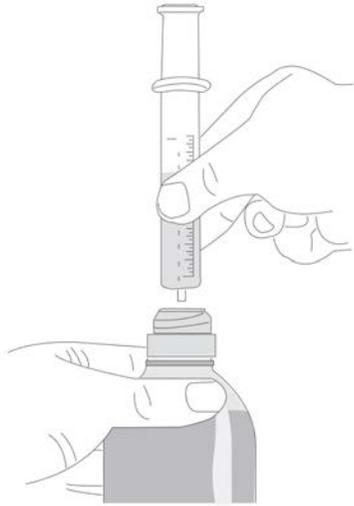
Step 9. Tap oral dosing syringe to move air bubbles to the top. Doing this helps set the correct dose.

Step 10. Push the plunger back slowly just far enough to completely push out any large or small air bubbles that may be trapped in the oral dosing syringe.



Step 11. Slowly pull the plunger down until the top edge of the plunger is level with the marker on the syringe barrel for the prescribed dose.

Note: If the prescribed dose is more than 10 mL, you will need to refill the oral dosing syringe to make up the full dose.



Step 12. Carefully turn the bottle upright. Take out the oral dosing syringe by gently twisting it out of the plastic adapter. The plastic adapter should stay in the bottle.

Taking the dose of RALDESY oral solution



Note: Sit up straight while taking RALDESY.

Step 13. Place the oral dosing syringe gently into your mouth. Push the plunger **slowly** until the plunger moves all of the medicine out of the oral dosing syringe.

Step 14. Swallow all of the medicine.

Step 15. Close the bottle by screwing the child-resistant cap back on the bottle after use. Make sure the child-resistant cap is tightly closed.

Step 16. Cleaning: After use, rinse the oral dosing syringe with warm water and allow it to dry thoroughly.

Step 17. Throw away (discard): Safely throw away medicine that is expired or no longer needed. Do not throw away any medicine down the sink or in your household trash. Ask your pharmacist how to throw away medicines you no longer use.

Storing RALDESY

- Store RALDESY at room temperature between 68°F to 77°F (20°C to 25°C).
- RALDESY comes in a bottle with a child-resistant cap.
- Keep RALDESY out of the light.
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