

RALDESY™

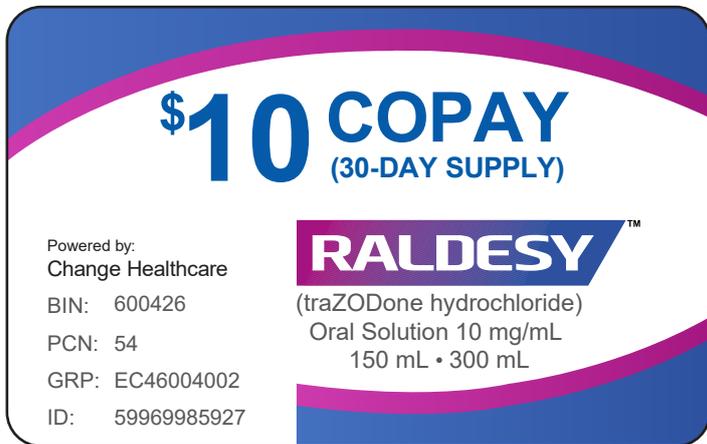
(traZODone hydrochloride) Oral Solution 10 mg/mL



\$10 COPAY

(30-DAY SUPPLY)

Please see Important Safety Information on reverse side, including Boxed Warning below



Congratulations!

Eligible* patients with commercial insurance pay a minimum of \$10 for a 30-day supply and receive up to \$200 off (maximum out of pocket \$75). For 31–90-day supply, patients pay a minimum of \$20 and receive up to \$300 off (maximum out of pocket \$150).

Here's how it works:

You pay the first \$10 of your copay, and then we'll pay up to the next \$200. Print your copay card and present it whenever you fill in your prescription at the pharmacy.

* Limitations and restrictions apply. To view eligibility requirements and terms and conditions, please visit raldesy.com or call 877-384-1417 for more information.

Patient Instructions: To redeem this copay card, you must have a valid prescription for **RALDESY™ (trazodone hydrochloride) Oral Solution**. Follow the dosage instructions given by your doctor. For a 30-day supply, you will be required to pay the first \$10 of your copay, after which this copay card will deduct up to \$200 off from your remaining balance (maximum out of pocket \$75). For 31–90-day supply, you will be required to pay the first \$20 of your copay, after which this copay card will deduct up to \$300 off from your remaining balance (maximum out of pocket \$150). The pharmacist will process your insurance information and this copay card and then inform you of your copay amount. This offer may not be redeemed for cash. By using this copay card, you are certifying that you meet the eligibility criteria and will comply with the terms and conditions described in the Restrictions section below. Limitations and restrictions apply. To view eligibility requirements and terms and conditions, please visit raldesy.com or call 1-800-433-4893 for more information.

Pharmacist instructions for a Patient paying with an Eligible Third-Party Payer: First submit this claim to the eligible commercial insurer as the primary payer, then submit the balance due to **Change Healthcare** as a Secondary Payer COB [coordination of benefits] with the patient responsibility amount and a valid Other Coverage Code (e.g., 8). For a 30-day supply, the patient is responsible for the first \$10 and this copay card pays up to the next \$200 off (maximum out of pocket \$75). For 31–90-day supply, the patient is responsible for the first \$20 and this copay card pays up to the next \$300 off (maximum out of pocket \$150). Reimbursement will be received from **Change Healthcare**.

Restrictions: This program is for commercially insured patients and requires a valid prescription for Raldesy. This offer is not valid for any patient receiving prescription reimbursement under any federal, state, or other government-funded programs such as Medicare, Medicare Advantage, Medicare Part D, Medicaid, Medigap, Veterans Affairs (VA), the Department of Defense (DoD) or TRICARE, or where prohibited by law. By accepting this benefit, you are certifying that: (1) you are not a beneficiary of any government-funded healthcare programs; (2) you will discontinue participating if you begin receiving prescription drug benefits from any government-funded healthcare programs; and (3) you will not seek reimbursement for value received from this offer from any third-party payers, including flexible spending accounts or healthcare savings accounts. Maximum benefit limitations and other restrictions apply. Call 877-384-1417 for complete program terms and conditions. This offer is subject to change or discontinuation without notice. This is not health insurance. For questions regarding eligibility or benefits, or to discontinue participation, call 1-800-433-4893.

This offer is not transferable. Not valid if reproduced. Void where prohibited by law. Program managed by ConnectiveRx on behalf of Validus Pharmaceuticals LLC. The parties reserve the right to rescind, revoke, or amend this offer without notice at any time.

IMPORTANT SAFETY INFORMATION

WARNING: SUICIDAL THOUGHTS and BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors. RALDESY is not approved for use in pediatric patients.

For full Important Safety Information including **Boxed WARNING** see reverse side



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INDICATIONS AND USAGE

RALDESY™ is indicated for the treatment of major depressive disorder (MDD) in adults.

ADMINISTRATION

Administer RALDESY orally after a meal or light snack.

CONTRAINDICATIONS

RALDESY is contraindicated in patients taking, or within 14 days of stopping, monoamine oxidase inhibitors (MAOIs), including MAOIs such as linezolid or intravenous methylene blue, because of an increased risk of serotonin syndrome.

WARNINGS AND PRECAUTIONS

Suicidal Thoughts and Behaviors in Pediatric and Young Adult Patients: It is unknown whether the risk of suicidal thoughts and behaviors in pediatric and young adult patients extends to longer-term use, i.e., beyond four months. Monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors, especially during the initial few months of drug therapy and at times of dosage changes. Counsel family members or caregivers of patients to monitor for changes in behavior and to alert the healthcare provider. Consider changing the therapeutic regimen, including possibly discontinuing RALDESY, in patients whose depression is persistently worse, or who are experiencing emergent suicidal thoughts or behaviors.

Serotonin Syndrome: Selective serotonin reuptake inhibitors (SSRIs), including RALDESY, can precipitate serotonin syndrome, a potentially life-threatening condition. The risk is increased with concomitant use of other serotonergic drugs (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John's Wort) and with drugs that impair metabolism of serotonin, i.e., MAOIs. Serotonin syndrome can also occur when these drugs are used alone. The concomitant use of RALDESY with MAOIs is contraindicated. In addition, do not initiate RALDESY in a patient being treated with MAOIs such as linezolid or intravenous methylene blue. If it is necessary to initiate treatment with an MAOI such as linezolid or intravenous methylene blue in a patient taking RALDESY, discontinue RALDESY before initiating treatment with the MAOI. Monitor all patients taking RALDESY for the emergence of serotonin syndrome. Discontinue treatment with RALDESY and any concomitant serotonergic agents immediately if the above symptoms occur, and initiate supportive symptomatic treatment.

Cardiac Arrhythmias: RALDESY should be avoided in patients with a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes and/or sudden death, including symptomatic bradycardia, hypokalemia or hypomagnesemia, and the presence of congenital prolongation of the QT interval. RALDESY is not recommended for use during the initial recovery phase of myocardial infarction. Caution should be used when administering RALDESY to patients with cardiac disease and such patients should be closely monitored, since antidepressant drugs (including RALDESY) may cause cardiac arrhythmias.

Orthostatic Hypotension and Syncope: Hypotension, including orthostatic hypotension and syncope has been reported in patients receiving trazodone hydrochloride. Concomitant use with an antihypertensive may require a reduction in the dose of the antihypertensive drug.

Increased Risk of Bleeding: Inform patients about the risk of bleeding associated with the concomitant use of RALDESY and antiplatelet agents or anticoagulants. For patients taking warfarin, carefully monitor coagulation indices when initiating, titrating, or discontinuing RALDESY.

Priapism: RALDESY should be used with caution in males who have conditions that might predispose them to priapism (e.g., sickle cell anemia, multiple myeloma, or leukemia), or in men with anatomical deformation of the penis (e.g., angulation, cavernosal fibrosis, or Peyronie's disease).

Activation of Mania or Hypomania: In patients with bipolar disorder, treating a depressive episode with RALDESY or another antidepressant may precipitate a mixed/manic episode. Activation of mania/hypomania has been reported in a small proportion of patients with major affective disorder who were treated with antidepressants. Prior to initiating treatment with RALDESY, screen patients for any personal or family history of bipolar disorder, mania, or hypomania.

Discontinuation Syndrome: Adverse reactions after discontinuation of serotonergic antidepressants, particularly after abrupt discontinuation, include: nausea, sweating, dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesia, such as electric shock sensations), tremor, anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. A gradual reduction in dosage rather than abrupt cessation is recommended whenever possible.

Potential for Cognitive and Motor Impairment: RALDESY™ may cause somnolence or sedation and may impair the mental and/or physical ability required for the performance of potentially hazardous tasks. Patients should be cautioned about operating machinery, including automobiles, until they are reasonably certain that the drug treatment does not cause them drowsiness.

Angle-Closure Glaucoma: The pupillary dilation that occurs following use of many antidepressant drugs (including RALDESY) may trigger an angle closure attack in a patient with anatomically narrow angles who does not have a patent iridectomy. Avoid use of antidepressants, including RALDESY, in patients with untreated anatomically narrow angles.

Hyponatremia: Hyponatremia may occur as a result of treatment with SSRIs and serotonin and norepinephrine reuptake inhibitors (SNRIs), including RALDESY. Cases with serum sodium lower than 110 mmol/L have been reported. Signs and symptoms of hyponatremia include headache, difficulty concentrating, memory impairment, confusion, weakness, and unsteadiness, which can lead to falls. Signs and symptoms associated with more severe and/or acute cases have included hallucination, syncope, seizure, coma, respiratory arrest, and death.

In many cases, this hyponatremia appears to be the result of the syndrome of inappropriate antidiuretic hormone secretion (SIADH). In patients with symptomatic hyponatremia, discontinue RALDESY and institute appropriate medical intervention. Elderly patients, patients taking diuretics, and those who are volume-depleted may be at greater risk of developing hyponatremia with SSRIs and SNRIs. See *Full Prescribing Information for additional warnings and precautions associated with RALDESY.*

ADVERSE REACTIONS

The following serious adverse reactions are described elsewhere in the labeling: Suicidal Thoughts and Behaviors in Pediatric and Young Adult Patients, Serotonin Syndrome, Cardiac Arrhythmias, Orthostatic Hypotension and Syncope, Increased Risk of Bleeding, Priapism, Activation of Mania or Hypomania, Discontinuation Syndrome, Potential for Cognitive and Motor Impairment, Angle-Closure Glaucoma and Hyponatremia.

To report SUSPECTED ADVERSE REACTIONS, contact Validus Pharmaceuticals LLC at 1-866-982-5438 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. See *Full Prescribing Information for additional adverse reactions associated with RALDESY.*

DRUG INTERACTIONS

Monoamine Oxidase Inhibitors (MAOIs): RALDESY is contraindicated in patients taking MAOIs, including MAOIs such as linezolid or intravenous methylene blue.

Other Serotonergic Drugs: Monitor patients for signs and symptoms of serotonin syndrome, particularly during RALDESY initiation. If serotonin syndrome occurs, consider discontinuation of RALDESY and/or concomitant serotonergic drugs.

Antiplatelet Agents and Anticoagulants: Inform patients of the increased risk of bleeding with the concomitant use of RALDESY and antiplatelet agents and anticoagulants. For patients taking warfarin, carefully monitor the international normalized ratio (INR) when initiating or discontinuing RALDESY.

Strong CYP3A4 Inhibitors: If RALDESY is used with a potent CYP3A4 inhibitor, the risk of adverse reactions, including cardiac arrhythmias, may be increased and a lower dose of RALDESY should be considered.

Strong CYP3A4 Inducers: Patients should be closely monitored to see if there is a need for an increased dose of RALDESY when taking CYP3A4 inducers.

Digoxin and Phenytoin: Patient serum digoxin or phenytoin concentrations should be measured before initiating concomitant use of RALDESY. Continue monitoring and reduce digoxin or phenytoin dose as necessary.

Central Nervous System (CNS) Depressants: Patients should be counseled that RALDESY may enhance the response to alcohol, barbiturates, and other CNS depressants.

QT Interval Prolongation: Avoid the use of RALDESY in combination with other drugs known to prolong QT. See *Full Prescribing Information for additional potential drug interactions associated with RALDESY.*

USE IN SPECIFIC POPULATIONS

Pregnancy: There are risks associated with untreated depression in pregnancy. Trazodone hydrochloride has been shown to cause increased fetal resorption and other adverse effects on the fetus in the rat when given at dose levels approximately 7.3 to 11 times the maximum recommended human dose (MRHD) of 400 mg/day in adults on a mg/m² basis.

Pregnancy Exposure Registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to antidepressants during pregnancy. Healthcare providers should encourage patients to enroll by calling the National Pregnancy Registry for Antidepressants at 1-866-961-2388 or visiting online at <https://womensmentalhealth.org/research/pregnancyregistry/antidepressants/>.

Lactation: The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for RALDESY and any potential adverse effects on the breastfed child from RALDESY or from the underlying maternal condition.

Pediatric Use: Safety and effectiveness of RALDESY in pediatric patients have not been established. Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric patients.

Geriatric Use: Serotonergic antidepressants have been associated with cases of clinically significant hyponatremia in elderly patients, who may be at greater risk for this adverse reaction.

Renal Impairment: RALDESY should be used with caution in this population.

Hepatic Impairment: RALDESY should be used with caution in this population.

DOSAGE FORMS AND STRENGTHS

RALDESY (10 mg/mL) Oral Solution: Clear, colorless solution. RALDESY is available only by prescription.

OVERDOSAGE

Death from overdose has occurred in patients concurrently ingesting trazodone and other CNS depressant drugs (e.g., alcohol; alcohol and chloral hydrate and diazepam; amobarbital; chlordiazepoxide; or meprobamate). The most severe reactions reported to have occurred with overdose of trazodone alone have been priapism, respiratory arrest, seizures, and ECG changes, including QT prolongation. The reactions reported most frequently have been drowsiness and vomiting. Overdosage may cause an increase in incidence or severity of any of the reported adverse reactions. There is no specific antidote for trazodone hydrochloride overdose. Consider contacting the Poison Help line at 1-888-222-1222 or a medical toxicologist for additional overdose management recommendations.

Please see Full Prescribing Information including Boxed WARNING at www.raldesy.com.

