Actor portrayal.

Adding an Atypical Antipsychotic in MDD:

WHY NOT EARLIER?

INDICATION

REXULTI® (brexpiprazole) is indicated for:

- Use as an adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) in adults

IMPORTANT SAFETY INFORMATION

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at increased risk of death. REXULTI is not approved for the treatment of patients with dementia-related psychosis without agitation associated with dementia due to Alzheimer's disease.

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behaviors in patients aged 24 years and younger. Monitor for clinical worsening and emergence of suicidal thoughts and behaviors. The safety and effectiveness of REXULTI have not been established in pediatric patients with MDD.

Please see IMPORTANT SAFETY INFORMATION on pages 10 and 11.

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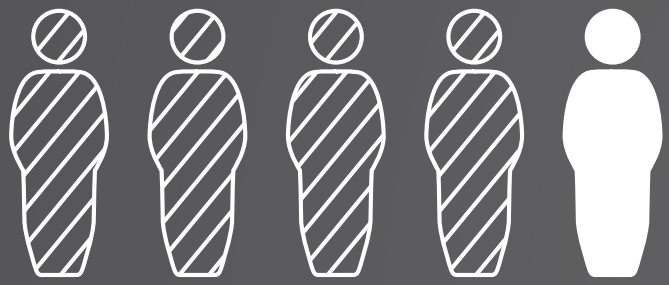
In order to overcome a partial response, many MDD patients need more than an antidepressant alone



In the STAR*D study, **>4 OUT OF 5** patients continued to have a partial response after their second antidepressant treatment[1,a]

[a]As demonstrated in almost 3700 adult patients with MDD who were prescribed antidepressants. *In the STAR*D study, partial response was defined as a less-than-50% reduction from treatment step entry in Quick Inventory of Depressive Symptomatology Self-Report score at 12-14 weeks.* The patient sample received successive acute treatment steps: 3671 patients entered at Step 1; 1439 patients continued at Step 2; 390 patients proceeded to Step 3; 123 patients advanced through all 4 steps. After SSRI monotherapy in Step 1, treatment options included switching medications or augmentation with either medication or cognitive therapy. Adjunctive atypical antipsychotics were not included at any step. Patients who either did not achieve response with a treatment or were unable to tolerate a treatment were encouraged to move to the next step.[1]

SSRI, selective serotonin reuptake inhibitor; STAR*D, Sequenced Treatment Alternatives to Relieve Depression.

Despite evidence supporting appropriate use, adjunctive atypical antipsychotics were prescribed late in the MDD treatment journey[2]

A chart review study showed that a patient may undergo **~5 TREATMENT CHANGES** before being prescribed an adjunctive atypical antipsychotic[2]

68% **greater chance of a response**

The chance of response increased by 68% in patients treated with adjunctive atypical antipsychotics vs antidepressant treatments alone (odds ratio=1.68) according to a meta-analysis[3,a]

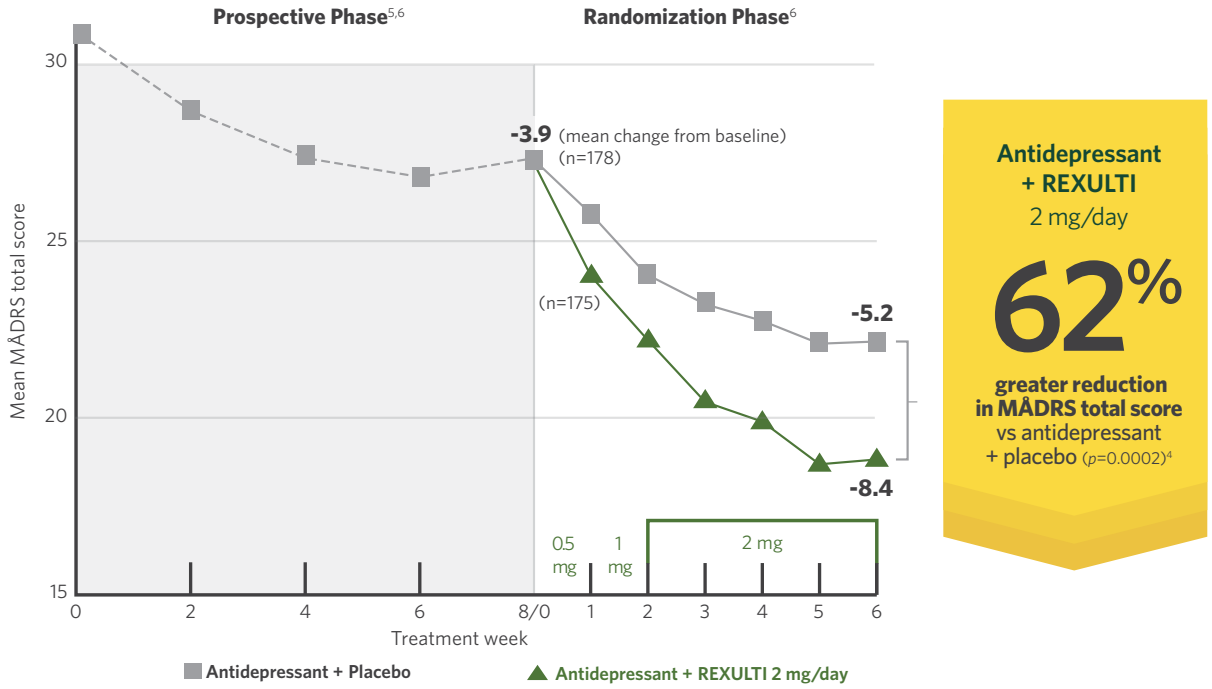
[a]In a meta-analysis, response was defined as a 50% improvement from baseline to endpoint on either the MÅDRS or HAM-D17. Meta-analysis included 17 randomized trials with 3807 patients (duration range: 4-12 weeks) comparing adjunctive antipsychotic treatment to SSRI/SNRI treatment in adult patients (age range: 18-65 years) with MDD. There was a 68% greater chance of response from the antidepressant + adjunctive antipsychotic group vs the antidepressant + placebo group.[3]

HAM-D17, 17-item Hamilton Depression Rating Scale; MÅDRS, Montgomery-Åsberg Depression Rating Scale; SNRI, serotonin and norepinephrine reuptake inhibitor.

When taken with an antidepressant,

Adding REXULTI® (brexpiprazole) amplified antidepressant symptom response vs placebo[4]

Adult patients in the ADT + REXULTI 2-mg/day arm experienced a 62% greater reduction in MÅDRS total score



Antidepressant + REXULTI
2 mg/day

62%

greater reduction in MÅDRS total score
vs antidepressant + placebo (p=0.0002)[4]

It is unknown if the differences observed at time points earlier than Week 6 represent clinically relevant treatment effects.

Mean MÅDRS before prospective treatment (SD): 31.0 (4.7). Mean MÅDRS after prospective treatment (SD): 27.1 (5.7). Mean MÅDRS at randomization (SD): ADT + placebo (n=178), 27.3 (5.6); ADT + REXULTI 2 mg/day (n=175), 26.9 (5.7).[5]

MDD STUDY DESIGN AND EFFICACY SUMMARY

REXULTI was studied in two 6-week, double-blind, placebo-controlled, fixed-dose pivotal trials of adult patients meeting DSM-IV-TR criteria for MDD. After a screening phase of 1-4 weeks, patients entered into an 8-week prospective treatment phase with an SSRI or SNRI. Subsequently, patients having persistent symptoms without substantial improvement throughout the course of treatment and who met inclusion criteria were randomized to receive adjunctive REXULTI or placebo.[6,7]

Primary endpoint was the mean change from baseline to Week 6 in the MÅDRS total score in the randomization phase.[6,7]

In the second pivotal trial, at the 3 mg/day maximum dose, the mean change from baseline (SE) at 6 weeks (randomized phase) was -8.3 (0.5) for ADT + REXULTI (n=213) vs -6.3 (0.5) for ADT + placebo (n=203), and the MÅDRS baseline (SD) for ADT + REXULTI and ADT + placebo was 26.5 (5.3) and 26.5 (5.2), respectively.[7]

The efficacy and safety of REXULTI were also studied in patients randomized to receive 1 mg/day in Study 2 (n=211). Results for the ADT + REXULTI 1 mg group for the primary efficacy parameter were not statistically significant when compared with ADT + placebo.[7]

ADT, antidepressant treatment; DSM-IV-TR, Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (Text Revision); SD, standard deviation; SE, standard error.

Contraindication

In patients with known hypersensitivity to brexpiprazole or any of its components. Reactions have included: rash, facial swelling, urticaria and anaphylaxis.

Please see IMPORTANT SAFETY INFORMATION on pages 10 and 11.

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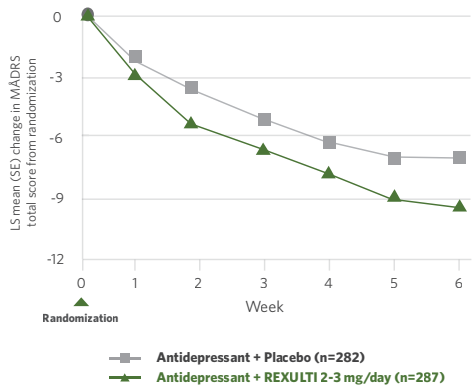
Post-hoc analysis

REXULTI® (brexpiprazole) + ADT change in MÅDRS total score in adult patients with MDD—with or without symptoms of anxiety

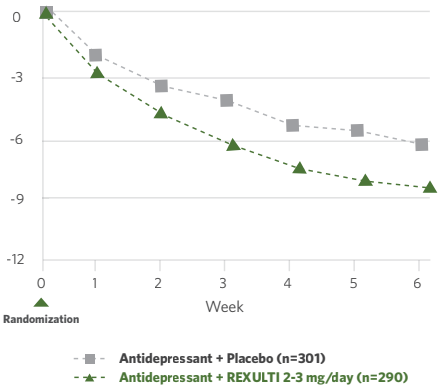
Using pooled data from 3 similarly designed 6-week randomized studies, including both 2 mg and 3 mg doses, changes were evaluated in MÅDRS total score in patients with MDD—with and without symptoms of anxiety.[6-8,a,b]

Effect on MÅDRS total score in patients with MDD, stratified by the presence or absence of symptoms of anxiety at baseline:

Patients with MDD **with** symptoms of anxiety



Patients with MDD **without** symptoms of anxiety



Study limitations: These analyses did not assess the effect of treatment on symptoms of anxiety. Patients with anxiety symptoms had a higher MÅDRS total score at baseline and the effects of anxiety and illness severity on outcomes were not differentiated. Statistical adjustments were not made for multiple comparisons, potentially inflating the type 1 error rate.

Adding REXULTI reduced mean MÅDRS total score by over 2 points in patients with MDD with or without symptoms of anxiety[8]:

- For patients with symptoms of anxiety, the LS mean change at Week 6 between ADT + REXULTI 2-3 mg/day and ADT + placebo was -2.19 (95% CI: -3.60 to -0.78)
- For patients without symptoms of anxiety, the LS mean change at Week 6 between ADT + REXULTI 2-3 mg/day and ADT + placebo was -2.34 (95% CI: -3.58 to -1.10)

[a]Baseline demographics and clinical characteristics were similar between treatment subgroups; however, patients with symptoms of anxiety were more likely to be female and have a higher MÅDRS total score at baseline compared with patients without symptoms of anxiety.[8]

[b]Of the patients that received an ADT plus REXULTI 2 mg, 3 mg, or placebo, 49% had symptoms of anxiety, defined as a score of ≥7 at baseline on the HAM-D anxiety/somatization factor.[8]

CI, confidence interval; HAM-D, Hamilton Rating Scale for Depression; LS, least squares.

Cerebrovascular Adverse Events, Including Stroke

In clinical trials, elderly patients with dementia randomized to risperidone, aripiprazole, and olanzapine had a higher incidence of stroke and transient ischemic attack, including fatal stroke. REXULTI is not approved for the treatment of patients with dementia-related psychosis without agitation associated with dementia due to Alzheimer's disease.

Please see IMPORTANT SAFETY INFORMATION on pages 10 and 11.

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REXULTI® (brexpiprazole) + antidepressants: safety profile in adult patients with MDD

Adverse reactions that occurred in ≥2% of patients and with greater incidence than placebo from two 6-week pivotal trials across all doses

Rates for ADT[a] + REXULTI (all doses; n=643) **vs ADT[a] + placebo** (n=411)

- **Akathisia:** 9% vs 2%
- **Headache:** 7% vs 6%
- **Weight increase:** 7% vs 2%
- **Somnolence:** 5% vs 0.5%
- **Nasopharyngitis:** 4% vs 2%
- **Tremor:** 4% vs 2%
- **Fatigue:** 3% vs 2%
- **Increased appetite:** 3% vs 2%
- **Anxiety:** 3% vs 1%
- **Dizziness:** 3% vs 1%
- **Restlessness:** 3% vs 0%
- **Blood cortisol decrease:** 2% vs 1%
- **Constipation:** 2% vs 1%

The **most common adverse reactions** (≥5%) and at least twice the rate of placebo for ADT + REXULTI vs ADT + placebo were weight increased (7% vs 2%), somnolence (5% vs 0.5%), and akathisia (9% vs 2%).

Two adverse reactions were dose-dependent

	ADT[a] + REXULTI (n=643)			ADT[a] + Placebo (n=411)
	1 mg n=226	2 mg n=188	3 mg n=229	
Akathisia	4%	7%	14%	2%
Restlessness	2%	3%	4%	0%

▶ A majority of the akathisia cases reported were mild or moderate[9]

[a]The antidepressants studied included SSRIs and SNRIs.
The safety population included patients randomized between 1 mg/day and 3 mg/day of ADT + REXULTI.

Neuroleptic Malignant Syndrome (NMS)

NMS is a potentially fatal symptom complex reported in association with administration of antipsychotic drugs, including REXULTI. Clinical signs of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis and cardiac dysrhythmia). Additional signs may include elevated creatinine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. Manage NMS with immediate discontinuation of REXULTI, intensive symptomatic treatment, and monitoring.

Please see IMPORTANT SAFETY INFORMATION on pages 10 and 11.

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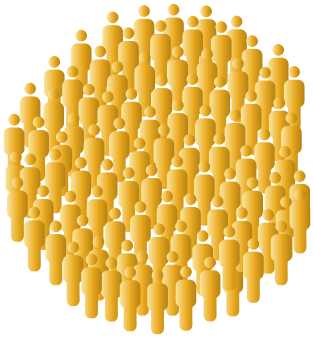
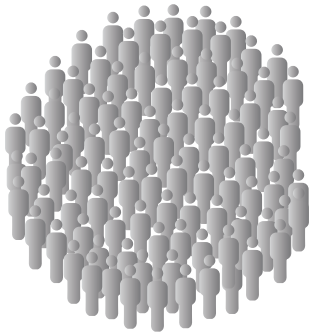
REXULTI® (brexpiprazole) + antidepressants: few discontinuations due to adverse reactions over 6 weeks across all doses

Discontinuation rates for antidepressant treatment + REXULTI vs antidepressant treatment + placebo



3%

ADT + REXULTI
(n=643)



1%

ADT + Placebo
(n=411)

In patients taking ADT + REXULTI (n=643, all doses) vs ADT + placebo (n=411), the rate of discontinuation due to akathisia was 0.9% vs 0% and the rate of discontinuation due to weight gain was 0% vs 0%, respectively[10,11]

Tardive Dyskinesia (TD)

Risk of TD, and the potential to become irreversible, appear to increase with duration of treatment and total cumulative dose of antipsychotic drugs. TD can develop after relatively brief treatment periods, at low doses, or after discontinuation of treatment. For chronic treatment, use the lowest dose and shortest duration of REXULTI needed to produce a clinical response. If signs and symptoms of TD appear, drug discontinuation should be considered.

Please see IMPORTANT SAFETY INFORMATION on pages 10 and 11.

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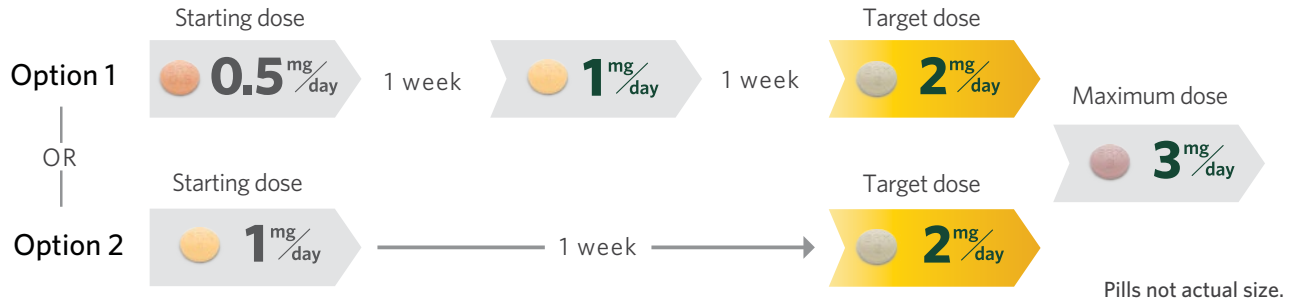
Dosing information for REXULTI® (brexpiprazole) as adjunctive treatment in adults in MDD

REXULTI—recommended target dose: 2 mg/day



- Dose increases should occur at weekly intervals based on the patient's clinical response and tolerability, and should be periodically reassessed to determine the continued need and appropriate dose for treatment

2 mg/day
Recommended dose

1 /day
Once-daily dosing

No food requirements

4-hour peak plasma concentration
(after administration)

Half-life

Dose adjustments for REXULTI

- Dose adjustments may be needed in patients with hepatic or renal impairment
- Administer half the dose of REXULTI when taken with strong CYP3A4 inhibitors or in patients who are known CYP2D6 poor metabolizers
- Administer a quarter of the dose with the concurrent use of both strong/moderate CYP2D6 inhibitors and strong/moderate CYP3A4 inhibitors. Likewise, administer a quarter of the dose in patients who are known CYP2D6 poor metabolizers taking strong/moderate CYP3A4 inhibitors
- Double the dose over 1 to 2 weeks when administering with strong CYP3A4 inducers

Please see IMPORTANT SAFETY INFORMATION on pages 10 and 11.

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Savings and Coverage

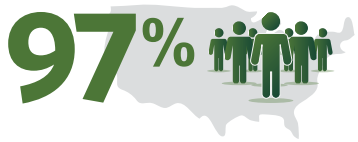
The REXULTI® (brexpiprazole) Savings Card offers **TWO** separate benefits: **REXULTI** as well as a **generic ANTIDEPRESSANT**[a]

REXULTI		
Two Months of REXULTI as little as	**$0**	✓
REXULTI Refills as little as	**$5**	✓
90-day Prescription as little as	**$5**	✓
Generic ANTIDEPRESSANT		
Generic ANTIDEPRESSANTS as little as[b]	**$0**	✓

[a]For eligible commercially insured patients who are prescribed REXULTI. Benefits apply to copays, co-insurance, and pharmacy deductibles. Maximum annual benefit applies based on current list price. See full Terms & Conditions at **www.REXULTI.com/savings-card-terms-conditions** for the current maximum benefit and more information.

[b]For up to 12 uses

REXULTI has broad national coverage and affordability support



OF PATIENTS NATIONALLY
have COVERAGE for REXULTI[12]

Helpful support resources for your patients are available at **REXULTI.com**—including the *REXULTI Savings Card* and *My Wellness Guide*.

Please see IMPORTANT SAFETY INFORMATION on pages 10 and 11.

References: 1. Rush AJ, Trivedi MH, Wisniewski SR, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report. *Am J Psychiatry*. 2006;163(11):1905-1917. **2.** McIntyre RS, Weiller E. Real-world determinants of adjunctive antipsychotic prescribing for patients with major depressive disorder and inadequate response to antidepressants: a case study review. *Adv Ther*. 2015;32(5):429-444. **3.** Wen XJ, Wang LM, Liu ZL, Huang A, Liu YY, Hu JY. Meta-analysis on the efficacy and tolerability of the augmentation of antidepressants with atypical antipsychotics in patients with major depressive disorder. *Braz J Med Biol Res*. 2014;47(7):605-616. **4.** Data on file (REX-014). **5.** Data on file (REX-284). **6.** Thase ME, Youakim JM, Skuban A, et al. Efficacy and safety of adjunctive brexpiprazole 2 mg in major depressive disorder: a phase 3, randomized, placebo-controlled study in patients with inadequate response to antidepressants. *J Clin Psychiatry*. 2015;76(9):1224-1231. **7.** Thase ME, Youakim JM, Skuban A, et al. Adjunctive brexpiprazole 1 and 3 mg for patients with major depressive disorder following inadequate response to antidepressants: a phase 3, randomized, double-blind study. *J Clin Psychiatry*. 2015;76(9):1232-1240. **8.** Thase ME, Weiller E, Zhang P, Weiss C, McIntyre RS. Adjunctive brexpiprazole in patients with major depressive disorder and anxiety symptoms: post hoc analyses of three placebo-controlled studies. *Neuropsychiatr Dis Treat*. 2019;15:37-45. **9.** Weiss C, Skuban A, Hobart M, Zhang P, Weiller E. Incidence, onset, duration and severity of akathisia with adjunctive brexpiprazole (OPC-34712) in major depressive disorder: analysis of two pivotal studies. Poster presented at: American Society of Clinical Psychopharmacology Annual Meeting; June 22-25, 2015; Miami, FL. **10.** Data on file (REX-022). **11.** Data on file (REX-034). **12.** Managed Markets Insights & Technology/Precision. Accessed July 2021.

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IMPORTANT SAFETY INFORMATION for REXULTI® (brexpiprazole)

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Antidepressants increased the risk of suicidal thoughts and behaviors in patients aged 24 years and younger. Monitor for clinical worsening and emergence of suicidal thoughts and behaviors. The safety and effectiveness of REXULTI have not been established in pediatric patients with MDD.

Contraindication: : In patients with known hypersensitivity to brexpiprazole or any of its components. Reactions have included: rash, facial swelling, urticaria and anaphylaxis.

Cerebrovascular Adverse Events, Including Stroke: In clinical trials, elderly patients with dementia randomized to risperidone, aripiprazole, and olanzapine had a higher incidence of stroke and transient ischemic attack, including fatal stroke. REXULTI is not approved for the treatment of patients with dementia-related psychosis without agitation associated with dementia due to Alzheimer's disease.

Neuroleptic Malignant Syndrome (NMS): NMS is a potentially fatal symptom complex reported in association with administration of antipsychotic drugs, including REXULTI. Clinical signs of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis and cardiac dysrhythmia). Additional signs may include elevated creatinine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. Manage NMS with immediate discontinuation of REXULTI, intensive symptomatic treatment, and monitoring.

Tardive Dyskinesia (TD): Risk of TD, and the potential to become irreversible, appear to increase with duration of treatment and total cumulative dose of antipsychotic drugs. TD can develop after relatively brief treatment periods, at low doses, or after discontinuation of treatment. For chronic treatment, use the lowest dose and shortest duration of REXULTI needed to produce a clinical response. If signs and symptoms of TD appear, drug discontinuation should be considered.

Metabolic Changes: Atypical antipsychotic drugs, including REXULTI, have caused metabolic changes including:

- **Hyperglycemia/Diabetes Mellitus:** Hyperglycemia and diabetes mellitus, in some cases extreme and associated with diabetic ketoacidosis, hyperosmolar coma or death, have been reported in patients treated with atypical antipsychotics. Assess fasting plasma glucose before or soon after initiation of antipsychotic medication and monitor periodically during long-term treatment.
- **Dyslipidemia:**Atypical antipsychotics cause adverse alterations in lipids. Before or soon after initiation of antipsychotic medication, obtain a fasting lipid profile at baseline and monitor periodically during treatment.
- **Weight Gain:** Weight gain has been observed in patients treated with REXULTI. Monitor weight at baseline and frequently thereafter.

Pathological Gambling and Other Compulsive Behaviors: Intense urges, particularly for gambling, and the inability to control these urges have been reported while taking REXULTI. Other compulsive urges have been reported less frequently. Prescribers should ask patients or their caregivers about the development of new or intense compulsive urges. Consider dose reduction or stopping REXULTI if such urges develop.

Please see FULL PRESCRIBING INFORMATION, including BOXED WARNING.

IMPORTANT SAFETY INFORMATION for REXULTI® (brexpiprazole) (continued)

Leukopenia, Neutropenia, and Agranulocytosis: Leukopenia and neutropenia have been reported with antipsychotics. Agranulocytosis (including fatal cases) has been reported with other agents in this class. Monitor complete blood count in patients with pre-existing low white blood cell count (WBC)/absolute neutrophil count or history of drug-induced leukopenia/neutropenia. Discontinue REXULTI at the first sign of a clinically significant decline in WBC and in patients with severe neutropenia.

Orthostatic Hypotension and Syncope: Atypical antipsychotics cause orthostatic hypotension and syncope. Generally, the risk is greatest during initial dose titration and when increasing the dose. Monitor in patients vulnerable to hypotension, and those with cardiovascular and cerebrovascular diseases.

Falls: Antipsychotics may cause somnolence, postural hypotension, motor, and sensory instability, which may lead to falls causing fractures or other injuries. For patients with diseases, conditions, or medications that could exacerbate these effects, complete fall risk assessments when initiating treatment and recurrently during therapy.

Seizures: REXULTI may cause seizures and should be used with caution in patients with a history of seizures or with conditions that lower the seizure threshold.

Body Temperature Dysregulation: Use REXULTI with caution in patients who may experience conditions that increase body temperature (e.g., strenuous exercise, extreme heat, dehydration, or concomitant use with anticholinergics).

Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotics, including REXULTI, and should be used with caution in patients at risk for aspiration.

Potential for Cognitive and Motor Impairment: REXULTI has the potential to impair judgment, thinking, or motor skills. Patients should be cautioned about operating hazardous machinery, including operating motor vehicles, until they are reasonably certain REXULTI does not affect them adversely.

Concomitant Medication: Dosage adjustments are recommended in patients who are known cytochrome P450 (CYP) 2D6 poor metabolizers and in patients taking concomitant CYP3A4 inhibitors or CYP2D6 inhibitors or strong CYP3A4 inducers.

Most commonly observed adverse reactions: In clinical trials of adults, the most common adverse reactions were:

- **Major Depressive Disorder (MDD)** (adjunctive treatment to antidepressant therapy; ≥5% incidence and at least twice the rate of placebo for REXULTI vs. placebo): weight increased, somnolence, and akathisia.

Dystonia: Symptoms of dystonia may occur in susceptible individuals during the first days of treatment and at low doses.

Pregnancy: Adequate and well-controlled studies to assess the risks of REXULTI during pregnancy have not been conducted. REXULTI should be used during pregnancy only if the benefit justifies the risk to the fetus.

Lactation: It is not known if REXULTI is excreted in human breast milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

To report SUSPECTED ADVERSE REACTIONS, contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch).

Please see FULL PRESCRIBING INFORMATION, including BOXED WARNING.

Adding REXULTI® (brexpiprazole) to an ADT amplified antidepressant symptom response vs placebo, with a 62% greater reduction in MÅDRS total score[4]

ADT + Placebo vs **ADT + REXULTI** 2 mg/day

62% greater reduction in MÅDRS total score with ADT + REXULTI[4]

LS mean change from baseline in MÅDRS total score:

- **2 mg/day recommended dose (SE):** -5.2 (0.6) for ADT + placebo vs -8.4 (0.6) for ADT + REXULTI[6]
- **3 mg/day maximum dose (SE):** -6.3 (0.5) for ADT + placebo vs -8.3 (0.5) for ADT + REXULTI[7]

	ADT + REXULTI (all doses)	ADT + Placebo
Weight increase	7%	2%
Somnolence	5%	0.5%
Akathisia	9%	2%

- The table above presents the most common adverse reactions that occurred in ≥5% of patients and at least twice the rate of placebo

Once you recognize partial response on an antidepressant, consider adding REXULTI

REXULTI was studied in two 6-week, double-blind, placebo-controlled, fixed-dose pivotal trials of adult patients meeting DSM-IV-TR criteria for MDD. After a screening phase of 1-4 weeks, patients entered into an 8-week prospective treatment phase with an SSRI or SNRI. Subsequently, patients having persistent symptoms without substantial improvement throughout the course of treatment and who met inclusion criteria were randomized to receive adjunctive REXULTI or placebo.[6,7]

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Otsuka Lundbeck

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