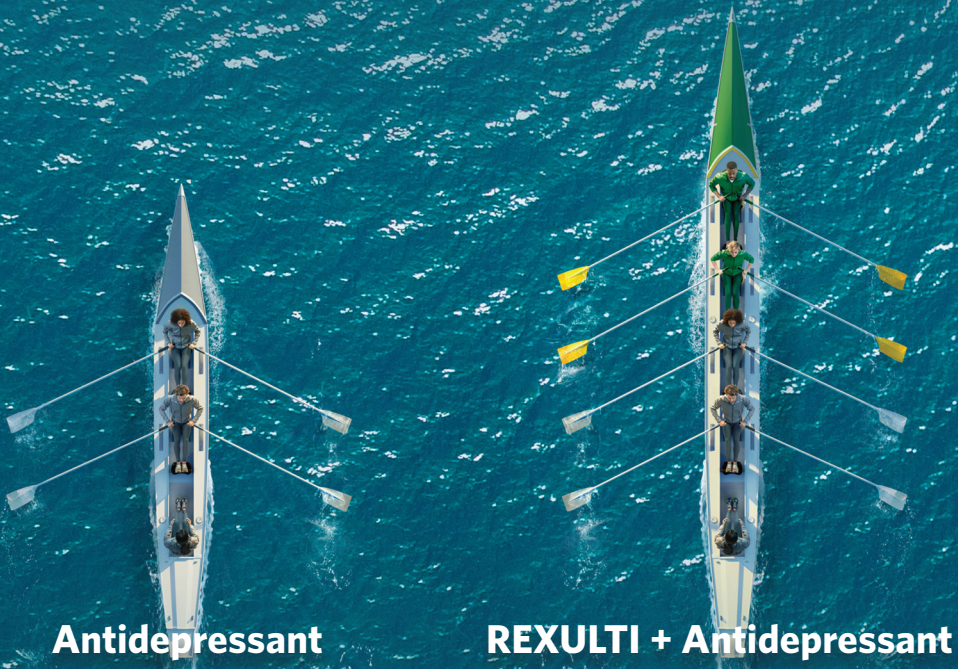
What's the next step for adult patients with MDD experiencing partial response on their antidepressant?

REXULTI®
brexpiprazole
2mg tablets



Antidepressant

REXULTI + Antidepressant

MDD, major depressive disorder.

INDICATION and IMPORTANT SAFETY INFORMATION for REXULTI® (brexpiprazole)

INDICATION

REXULTI 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 pediatric patients and young adult patients. Closely monitor all antidepressant-treated patients 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 12 and 13 and FULL PRESCRIBING INFORMATION, including **BOXED WARNING**.

Is partial response good enough?

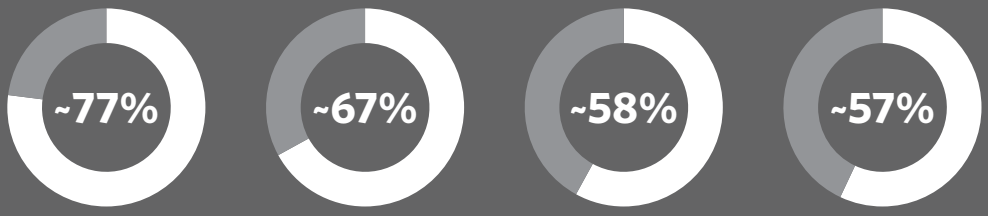
Major depression among adults in the US has continued to increase[1]

11 million Of an estimated 22 million US adults affected, approximately half, or 11 million, **may not fully respond to their antidepressant**[2,3,a]

Partial response has been defined as a **25-50% reduction from baseline in depression scale scores**[4,b]

MDD symptoms reported by adult patients on one or more antidepressant[5]

In one online survey, the most frequently reported symptoms other than those measured by the PHQ-9 were[5c]:



[a]Demonstrated in almost 3700 adult patients with MDD who were prescribed an SSRI. In the STAR*D study, inadequate response was defined as less than 50% reduction from treatment step entry in QIDS-SR16 score at 12 to 14 weeks. Statistic is an extrapolation of the STAR*D study.[2]

[b]The HAM-D has been the metric of choice for measuring depression in research settings. Other scales such as the MÅDRS and the Inventory for Depressive Symptomatology have also been used.[4]

[c]Based on an online survey of adult patients (n=2096) age 18-65 with an inadequate response to an antidepressant who reported symptoms occurring (1) several days to (3) nearly every day on the PHQ-9; current symptoms of depression were assessed with a modified PHQ-9 which excluded the question of suicidal ideation; non-PHQ-9 symptoms were elicited from a checklist of clinical symptoms associated with depression. In the survey, 38% of participants were taking combination antidepressant therapy (more than one antidepressant at the same time) and 16% were taking adjunctive atypical antipsychotics.[5]

HAM-D17, 17-item Hamilton Depression Rating Scale; MÅDRS, Montgomery-Åsberg Depression Rating Scale; MDD, major depressive disorder; PHQ-9, Patient Health Questionnaire-9; QIDS-SR16, Quick Inventory of Depressive Symptomatology Self-Report; SSRI, selective serotonin reuptake inhibitor; STAR*D, Sequenced Treatment Alternatives to Relieve Depression.

Please see **IMPORTANT SAFETY INFORMATION** on pages 12 and 13.

Despite evidence supporting appropriate use, a chart review study showed that a patient may undergo ~5 treatment changes before being prescribed an adjunctive atypical antipsychotic[6]

Decrease in response rate

Antidepressant treatment changes may affect response rates. In the STAR*D study, rates of response decreased with each additional switch in antidepressant treatment (48.6% in Step 1 to 16.3% in Step 4)[2,a]

Atypical antipsychotics may increase response rates for patients

68% greater chance of a response

According to a meta-analysis, the chance of response doubled in patients treated with adjunctive atypical antipsychotics vs antidepressant treatments alone (odds ratio=1.68)[7,b]

[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.[2]

[b]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.[7]

HAM-D17, 17-item Hamilton Depression Rating Scale; MÅDRS, Montgomery-Åsberg Depression Rating Scale; MDD, major depressive disorder; SNRI, serotonin and norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor; STAR*D, Sequenced Treatment Alternatives to Relieve Depression.

Please see **IMPORTANT SAFETY INFORMATION** on pages 12 and 13.

CONSIDER THE PROFILE OF THIS HYPOTHETICAL PATIENT BELOW:
OCCUPATION: Teacher, mother of two • **AGE:** 38

CURRENT MDD PRESENTATION:

- Partial response since switching from SSRI to SNRI, despite optimal dose/duration
- Current symptoms: pessimistic thoughts, ongoing sadness, excessive worry
- Expresses a reluctance to switch antidepressants
- Symptoms of anxiety

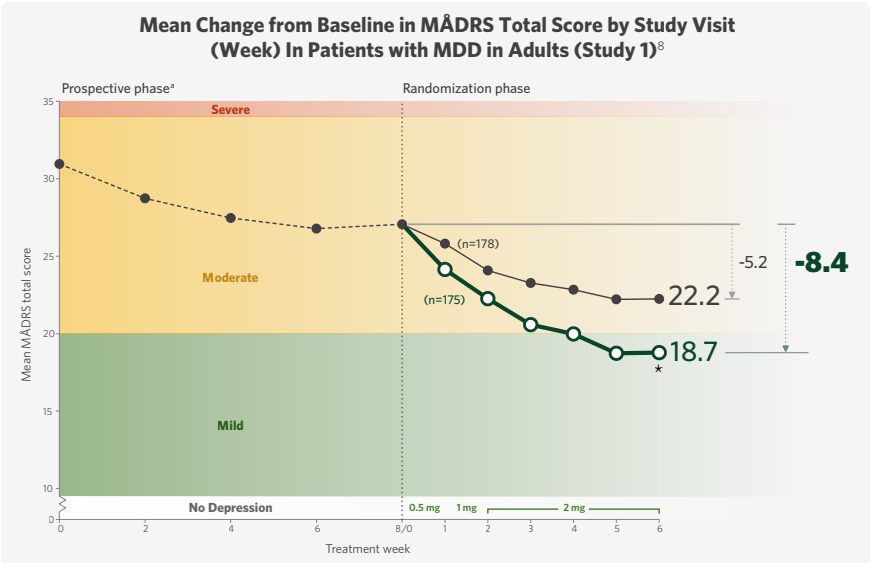
MDD, major depressive disorder; SNRI, serotonin and norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor.

An antidepressant alone may not be enough.
Have you asked your patients if they are experiencing a partial response?

Please see **IMPORTANT SAFETY INFORMATION** on pages 12 and 13.

When added to an antidepressant,

REXULTI® (brexpiprazole) 2 mg/day was superior in reducing mean MÅDRS total score vs antidepressant + placebo



Statistically significant reduction in mean MÅDRS total score vs antidepressant + placebo

- Antidepressant + placebo
- Antidepressant + placebo
- **Antidepressant + REXULTI 2 mg**

MÅDRS Total Scoring[9]

- **Severe Depression:** >34 MÅDRS total score
- **Moderate Depression:** 20 to 34 MÅDRS total score
- **Mild Depression:** 7 to 19 MÅDRS total score
- **No Depression:** 0 to 6 MÅDRS total score

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

[a]Not all patients had an inadequate response to antidepressant alone in the 8-week prospective phase. Only patients with an inadequate response entered the randomized double-blind treatment phase.

*$p<0.001$.

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).[8]

MDD study design and efficacy summary

The efficacy of REXULTI in the adjunctive treatment of MDD was evaluated in two 6-week, double-blind, placebo-controlled, fixed-dose studies of adult patients meeting DSM-IV-TR criteria for MDD, with or without symptoms of anxiety, who had an inadequate response to prior antidepressant therapy (1 to 3 courses) in the current episode. After a screening phase of 1-4 weeks, patients entered into an 8-week prospective treatment phase with an SSRI or SNRI (+ single-blind placebo). 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.[10,11]

In Study 2 for the REXULTI (3 mg/day) + ADT treatment group, the placebo-subtracted difference was -2.0 with a 95% CI (-3.4, -0.5).

Primary endpoint was the mean change from baseline to Week 6 in the MÅDRS total score in the randomization phase.[10,11]

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.[11]

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.[11]

ADT, antidepressant treatment; DSM-IV-TR, Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (Text Revision); MÅDRS, Montgomery-Åsberg Depression Rating Scale; MDD, major depressive disorder; SD, standard deviation; SE, standard error; SNRI, serotonin and norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor.

IMPORTANT SAFETY INFORMATION (cont'd)

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 12 and 13.

REXULTI® brexpiprazole 2mg tablets

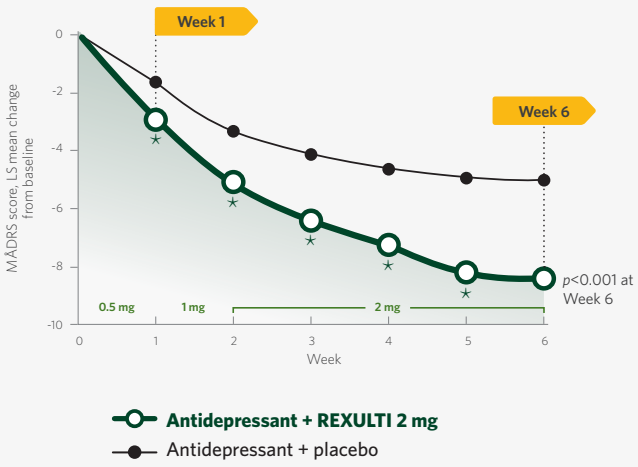
NON-PIVOTAL STUDY DATA

Additional analysis

REXULTI® (brexpiprazole) + antidepressant separated from antidepressant + placebo as early as Week 1 and continued to Week 6[10]

The weekly time points prior to Week 6 were not powered for statistical comparison and are descriptive only. Primary endpoint was the mean change from baseline to Week 6 in the MÅDRS total score in the randomization phase.[10]

Mean change in MÅDRS total score[10,a,b]



[a]Baseline mean MÅDRS scores were 27.3 for ADT + placebo (n=178) and 26.9 for ADT + REXULTI (n=175).

[b]*p* values are based on mixed model repeated-measures analysis.

**p*=nominal.

ADT, antidepressant treatment; LS, least squares; MÅDRS, Montgomery-Åsberg Depression Rating Scale.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

Please see **IMPORTANT SAFETY INFORMATION** on pages 12 and 13.

REXULTI® brexpiprazole 2mg tablets

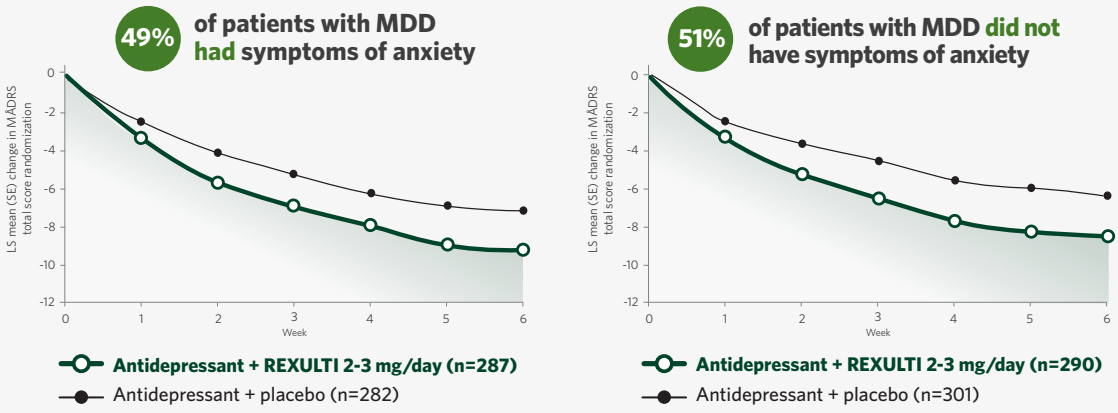
NON-PIVOTAL STUDY DATA

Post hoc analysis

REXULTI® (brexpiprazole) + antidepressant 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.[10-12,a,b]

Effect on MÅDRS total score in patients with MDD, stratified by the presence or absence of symptoms of anxiety at baseline[10-12]:



[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.[12]

[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.[12]

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.[12]

Adding REXULTI reduced mean MÅDRS total score by over 2 points in patients with MDD with or without symptoms of anxiety[12]:

- 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)

ADT, antidepressant treatment; HAM-D, Hamilton Rating Scale for Depression; LS, least squares; MÅDRS, Montgomery-Åsberg Depression Rating Scale; MDD, major depressive disorder; SE, standard error.

IMPORTANT SAFETY INFORMATION (cont'd)

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

Please see **IMPORTANT SAFETY INFORMATION** on pages 12 and 13.

REXULTI® brexpiprazole 2mg tablets

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 increase (7% vs 2%), somnolence (5% vs 0.5%), and akathisia (9% vs 2%).

- In patients taking ADT + REXULTI (n=643, all doses) vs ADT + placebo (n=411), the incidence of decreased libido was 0.6% vs 0.2%, respectively[13]

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[14]

[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.

ADT, antidepressant treatment; MDD, major depressive disorder; SNRI, serotonin and norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor.

IMPORTANT SAFETY INFORMATION (cont'd)

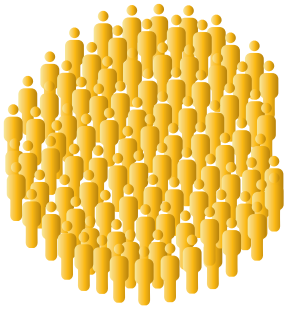
- **Hyperglycemia/Diabetes Mellitus:** Hyperglycemia and diabetes mellitus, in some cases extreme and associated with diabetic ketoacidosis, hyperosmolar coma, or death, have been reported in patients treated with atypical antipsychotics. Assess fasting plasma glucose before or soon after initiation of antipsychotic medication and monitor periodically during long-term treatment.

Please see **IMPORTANT SAFETY INFORMATION** on pages 12 and 13.

REXULTI® brexpiprazole 2mg tablets

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)

Discontinuations Due to Most Common Adverse Events

	ADT + REXULTI	ADT + Placebo
Due to akathisia[15]	0.9%	0%
Due to weight increase[16]	0%	0%
Due to somnolence[15]	0.2%	0%

ADT, antidepressant treatment.

IMPORTANT SAFETY INFORMATION (cont'd)

- **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 **IMPORTANT SAFETY INFORMATION** on pages 12 and 13.

REXULTI® brexpiprazole 2mg tablets

Change in libido with REXULTI® (brexpiprazole) + antidepressant across all doses[13]

In patients taking REXULTI + antidepressant (n=643, all doses), the incidence of decreased libido was 0.6%. For antidepressant + placebo (n=411), the incidence of decreased libido was 0.2%.

Decreased libido across all doses of antidepressant + REXULTI

	ADT + REXULTI (n=643) across all doses	ADT + Placebo (n=411)
Decreased Libido	0.6%	0.2%

ADT, antidepressant treatment.

IMPORTANT SAFETY INFORMATION (cont'd)

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, and 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 treatment.

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 (eg, strenuous exercise, extreme heat, dehydration, or concomitant use with anticholinergics).

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REXULTI® brexpiprazole 2mg tablets

Your patients are ready and we can help them get started

Connect With a Network of Pharmacies

The Integrated Pharmacy Network (IPN) has expertise in mental health and can help streamline the patient support process

- Supports faster time to therapy and the optimization of support offerings

covermymeds®

For Prior Authorization and Appeals support, Otsuka offers CoverMyMeds

Phone
1-866-452-5017

Website
www.covermymeds.com

Curious about local REXULTI coverage?

Scan QR code to learn more

Terms and conditions apply.

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

Scan QR code for support resources

IMPORTANT SAFETY INFORMATION (cont'd)

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

REXULTI® brexpiprazole 2mg tablets

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INDICATION and IMPORTANT SAFETY INFORMATION for REXULTI® (brexpiprazole)

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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 may cause somnolence and 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).

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Adding REXULTI to an ADT was superior to placebo plus ADT in reducing mean MÅDRS total scores

"I'm worried my progress has stalled. I'm a little better since switching antidepressants, but still feel down and I'm anxious about my performance at work. Is there more that could be done?"

—Kimberly
Actor portrayal.

Clinical Findings:
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[10]
- **3 mg/day maximum dose (SE):** -6.3 (0.5) for ADT + placebo vs -8.3 (0.5) for ADT + REXULTI[11]

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

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

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.[10,11]

ADT, antidepressant treatment; DSM-IV-TR, Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (Text Revision); LS, least squares; MÅDRS, Montgomery-Åsberg Depression Rating Scale; MDD, major depressive disorder; SE, standard error; SNRI, serotonin and norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor.

INDICATION

REXULTI 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 pediatric patients and young adult patients. Closely monitor all antidepressant-treated patients 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 12 and 13 and FULL PRESCRIBING INFORMATION, including **BOXED WARNING**.

REXULTI® brexpiprazole 2mg tablets

Otsuka Lundbeck

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