Still Having Depression Symptoms?



Is it time to tell your doctor what's really going on?

If you're taking an antidepressant and still struggling with depression symptoms, now's the time to talk to your doctor. Find out if adding REXULTI® (brexpiprazole) to your antidepressant may help you feel better by reducing your symptoms of depression.

If you've been on an antidepressant for at least 8 weeks and are still dealing with depression symptoms, ask about REXULTI a prescription medicine your doctor can add to your antidepressant that has been proven to reduce symptoms of depression. It may help you feel better without giving up the progress you may have already made. Not everyone responds to medication the same way, so talk to your doctor to see if REXULTI is right for you.

You can use the questions below to help you get the conversation started with your healthcare provider. **Print it out or save it to your mobile device and bring it to your next appointment.**

1.	I've made some progress on my antidepressant, but I'm still struggling with depression symptoms. Could adding REXULTI help?	5.	How should I take REXULTI—do I need to take it with food?
2.	I'm already on an antidepressant; would I have to stop taking it if I take REXULTI?	6.	How soon after starting REXULTI may I expect to see improvement in my depression symptoms?
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3.	I've already tried the following medications for my depression:	7.	What else should I know about REXULTI?
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4.	What are the possible side effects of REXULTI?	8.	Is there a REXULTI savings card?

INDICATION and IMPORTANT SAFETY INFORMATION for REXULTI® (brexpiprazole)

INDICATION: REXULTI is a prescription medicine used to treat:

• Major depressive disorder (MDD): REXULTI is used with antidepressant medicines, when your healthcare provider determines that an antidepressant alone is not enough to treat your depression.

It is not known if REXULTI is safe and effective in people under 18 years of age.

IMPORTANT SAFETY INFORMATION:

Increased risk of death in elderly people with dementia-related psychosis. Medicines like REXULTI can raise the risk of death in elderly who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). REXULTI is not approved for the treatment of patients with dementia-related psychosis.

Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, or young adults within the first few months of treatment. Depression and other serious mental illnesses are the most important causes of suicidal thoughts or actions. Some people may have a particularly high risk of having suicidal thoughts or actions. Patients on antidepressants and their families or caregivers should watch for new or worsening depression symptoms, especially sudden changes in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed. Report any changes in these symptoms immediately to the doctor. REXULTI is not approved for the treatment of people younger than 18 years of age.

Do not take REXULTI if you are allergic to brexpiprazole or any of the ingredients in REXULTI. Allergic reactions have included rash, facial swelling, hives and itching, and anaphylaxis, which may include difficulty breathing, tightness in the chest, and swelling of the mouth, face, lips, or tongue.

Please read FULL PRESCRIBING INFORMATION, including BOXED WARNING, and MEDICATION GUIDE.

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

REXULTI may cause serious side effects, including:

- Stroke in elderly people (cerebrovascular problems) that can lead to death.
- Neuroleptic Malignant Syndrome (NMS): Tell your healthcare provider right away if you have **some or all** of the following symptoms: high fever, stiff muscles, confusion, sweating, changes in pulse, heart rate, and blood pressure. These may be symptoms of a rare and serious condition that can lead to death. Call your healthcare provider right away if you have any of these symptoms.
- Uncontrolled body movements (tardive dyskinesia). REXULTI may cause movements that you cannot control in your face, tongue or other body parts. Tardive dyskinesia may not go away, even if you stop taking REXULTI. Tardive dyskinesia may also start after you stop taking REXULTI.
- Problems with your metabolism such as:
 - high blood sugar (hyperglycemia): Increases in blood sugar can happen in some people who take REXULTI.
 Extremely high blood sugar can lead to coma or death.
 If you have diabetes or risk factors for diabetes (such as being overweight or having a family history of diabetes), your healthcare provider should check your blood sugar before you start taking REXULTI and during your treatment.

Call your healthcare provider if you have any of these symptoms of high blood sugar while taking REXULTI:

- feel very thirsty
- feel very hungry
- feel sick to your stomach
- feel weak or tired
- need to urinate more than usual
- feel confused, or your breath smells fruity
- $^{\circ}$ increased fat levels (cholesterol and triglycerides) in your blood.
- weight gain. You and your healthcare provider should check your weight regularly.
- **Unusual urges.** Some people taking REXULTI have had unusual urges, such as gambling, binge eating or eating that you cannot control (compulsive), compulsive shopping and sexual urges.

If you or your family members notice that you are having unusual urges or behaviors, talk to your healthcare provider.

- Low white blood cell count
- Decreased blood pressure (orthostatic hypotension). You may feel lightheaded or faint when you rise too quickly from a sitting or lying position.
- Seizures (convulsions)
- Problems controlling your body temperature so that you feel too warm. Avoid getting over-heated or dehydrated while taking REXULTI.
 - **Do not** over-exercise.
 - Stay out of the sun. Do not wear too much or heavy clothing.
 - In hot weather, stay inside in a cool place if possible.
 - o Drink plenty of water.

• Difficulty swallowing that can cause food or liquid to get into your lungs.

Do not drive a car, operate machinery, or do other dangerous activities until you know how REXULTI affects you. REXULTI may make you feel drowsy.

Before taking REXULTI, tell your healthcare provider if you:

- have diabetes or high blood sugar or a family history of diabetes or high blood sugar. Your healthcare provider should check your blood sugar before you start REXULTI and during your treatment.
- have high levels of cholesterol, triglycerides, LDL-cholesterol, or low levels of HDL cholesterol
- have or had seizures (convulsions)
- have or had low or high blood pressure
- have or had heart problems or a stroke
- have or had a low white blood cell count
- are pregnant or plan to become pregnant. It is not known if REXULTI may harm your unborn baby. Using REXULTI in the last trimester of pregnancy may cause muscle movement problems, medicine withdrawal symptoms, or both of these in your newborn.
 - If you become pregnant while taking REXULTI, talk to your healthcare provider about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can register by calling 1-866-961-2388 or visit <u>http://</u> womensmentalhealth.org/clinical-and-researchprograms/pregnancyregistry/
- are breastfeeding or plan to breastfeed. It is not known if REXULTI passes into your breast milk. You and your healthcare provider should decide if you will take REXULTI or breastfeed.

Tell your healthcare provider about all the medicines you take or recently have taken, including prescription medicines, over-thecounter medicines, vitamins and herbal supplements.

REXULTI and other medicines may affect each other causing possible serious side effects. REXULTI may affect the way other medicines work, and other medicines may affect how REXULTI works.

Your healthcare provider can tell you if it is safe to take REXULTI with your other medicines. **Do not** start or stop any medicines while taking REXULTI without talking to your healthcare provider first.

The **most common side effects** of REXULTI include weight gain and an inner sense of restlessness such as feeling like you need to move.

Tell your healthcare provider if you experience abnormal muscle spasms or contractions, which may be a sign of a condition called dystonia.

These are not all the possible side effects of REXULTI. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about your health or medicines, including side effects.

You are encouraged to report side effects of REXULTI (brexpiprazole). Please 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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