

**MEDICATION GUIDE**  
**REXULTI<sup>®</sup> (REX-ul-TE)**  
**(brexpiprazole)**  
**Tablets**

**What is the most important information I should know about REXULTI?**

**REXULTI may cause serious side effects, including:**

- **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.
- **Risk of suicidal thoughts or actions.** Antidepressant medicines, depression and other serious mental illnesses, may cause suicidal thoughts or actions. REXULTI is not approved for the treatment of people younger than 18 years of age.
  - **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.** These include people who have (or have a family history of) bipolar illness (also called manic-depressive illness) or suicidal thoughts or actions.
  - **How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?**
    - Pay close attention to any changes, 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.
    - Call the healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
    - Keep all follow-up visits with the healthcare provider as scheduled. Call the healthcare provider between visits as needed, especially if you have concerns about symptoms.

**Call a healthcare provider right away if you or your family member has any of the following symptoms, especially if they are new, worse, or worry you:**

- |  |  |
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| ○ thoughts about suicide or dying                    | ○ attempts to commit suicide                 |
| ○ new or worsening depression                        | ○ new or worsening anxiety                   |
| ○ feeling very agitated or restless                  | ○ acting on dangerous impulses               |
| ○ panic attacks                                      | ○ trouble sleeping (insomnia)                |
| ○ new or worsening irritability                      | ○ acting aggressive, being angry, or violent |
| ○ an extreme increase in activity or talking (mania) | ○ other unusual changes in behavior or mood  |

**What else do I need to know about antidepressant medicines?**

- **Never stop an antidepressant medicine without first talking to your healthcare provider.** Stopping an antidepressant medicine suddenly can cause other symptoms.
- **Antidepressants are medicines used to treat depression and other illnesses.** It is important to discuss all the risks of treating depression and also the risks of not treating it. Patients and their families or other caregivers should discuss all treatment choices with the healthcare provider, not just the use of antidepressants.
- **Antidepressant medicines have other side effects.** Talk to the healthcare provider about the possible side effects of the medicine prescribed for you or your family member.
- **Antidepressant medicines can interact with other medicines.** Know all of the medicines that you or your family member takes. Keep a list of all medicines (including prescription medicines, non-prescription medicines, vitamins and herbal supplements) to show the healthcare provider. Do not start new medicines without first checking with your healthcare provider.

**What is REXULTI?**

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.
- Schizophrenia

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

**Who should not take REXULTI?**

**Do not take REXULTI if you** are allergic to brexpiprazole or any of the ingredients in REXULTI. See the end of this Medication Guide for a complete list of ingredients in REXULTI.

**What should I tell my healthcare provider before taking REXULTI?**

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 <http://womensmentalhealth.org/clinical-and-research-programs/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-the-counter 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.

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

**How should I take REXULTI?**

- Take REXULTI exactly as your healthcare provider tells you to take it. **Do not** change the dose or stop taking REXULTI yourself.
- REXULTI can be taken with or without food.
- You should **not** miss a dose of REXULTI. If you miss a dose, take the missed dose as soon as you remember. If you are close to your next dose, just skip the missed dose and take your next dose at your regular time. **Do not** take 2 doses of REXULTI at the same time. If you are not sure about your dosing, **call your healthcare provider**.
- If you take too much REXULTI, call your healthcare provider or Poison Control Center at **1-800-222-1222** right away, or go to the nearest hospital emergency room.

**What should I avoid while taking REXULTI?**

- **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.
- Avoid getting over-heated or dehydrated while taking REXULTI.
  - **Do not** over-exercise. ○ In hot weather, stay inside in a cool place if possible.
  - Stay out of the sun. **Do not** wear too much or heavy clothing. ○ Drink plenty of water.

**What are the possible side effects of REXULTI?**

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

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
  - **increased fat levels (cholesterol and triglycerides) in your blood.**
  - **weight gain:** You and your healthcare provider should check your weight regularly.

- **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.** See “**What should I avoid while taking REXULTI?**”
- **Difficulty swallowing that can cause food or liquid to get into your lungs.**

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

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 side effects. **You may report side effects to FDA at 1-800-FDA-1088.**

#### **How should I store REXULTI?**

Store REXULTI at room temperature, between 68°F to 77°F (20°C to 25°C).

**Keep REXULTI and all medicines out of the reach of children.**

#### **General information about the safe and effective use of REXULTI.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use REXULTI for a condition for which it was not prescribed. Do not give REXULTI to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about REXULTI. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about REXULTI that is written for healthcare professionals. **For more information about REXULTI, go to [www.REXULTI.com] or call 1-800-441-6763.**

#### **What are the ingredients in REXULTI?**

**Active ingredient:** brexpiprazole

**Inactive ingredients:** lactose monohydrate, corn starch, microcrystalline cellulose, hydroxypropyl cellulose, low-substituted hydroxypropyl cellulose, magnesium stearate, hypromellose, and talc.

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Distributed and Marketed by Otsuka America Pharmaceutical, Inc., Rockville, MD 20850 USA

Marketed by Lundbeck, Deerfield, IL 60015 USA

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

Approved: 08/2015