

MEDICATION GUIDE
REXULTI® (REX-ul-TE)
(brexpiprazole)
tablets, for oral use

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 people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). REXULTI is not approved for the treatment of people with dementia-related psychosis without agitation that may happen with dementia due to Alzheimer's disease.
- **Increased risk of suicidal thoughts and actions.** REXULTI and antidepressant medicines may increase suicidal thoughts and actions in some people 24 years of age and younger, **especially within the first few months of treatment or when the dose is changed.**

- Depression and other mental illnesses are the most important causes of suicidal thoughts and 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 REXULTI or the antidepressant medicine is started or when the dose is changed.
- Call your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings, or if you develop suicidal thoughts or actions.
- Keep all follow-up visits with your healthcare provider as scheduled. Call your 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 have 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 | ▪ panic attacks |
| ▪ trouble sleeping (insomnia) | ▪ new or worsening irritability |
| ▪ acting aggressive, being angry, or violent | ▪ acting on dangerous impulses |
| ▪ an extreme increase in activity or talking (mania) | ▪ other unusual changes in behavior or mood |

What is REXULTI?

REXULTI is a prescription medicine used:

- along with antidepressant medicines to treat major depressive disorder (MDD) in adults
- to treat schizophrenia in adults and children ages 13 years and older
- to treat agitation that may happen with dementia due to Alzheimer's disease

REXULTI should not be used as an "as needed" treatment for agitation that may happen with dementia due to Alzheimer's disease.

It is not known if REXULTI is safe and effective in children with MDD.

It is not known if REXULTI is safe and effective in children under 13 years of age with schizophrenia.

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.

Before taking REXULTI, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had heart problems or a stroke
- have or have had low or high blood pressure
- have or have had 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 treatment with REXULTI.
- have or have had high levels of total cholesterol, LDL cholesterol, or triglycerides, or low levels of HDL cholesterol
- have or have had seizures (convulsions)
- have or have had kidney or liver problems

- have or have had a low white blood cell count
- are pregnant or plan to become pregnant. REXULTI may harm your unborn baby. Taking REXULTI during your third trimester of pregnancy may cause your baby to have abnormal muscle movements or withdrawal symptoms after birth. Talk to your healthcare provider about the risk to your unborn baby if you take REXULTI during pregnancy.
 - Tell your healthcare provider if you become pregnant or think you are pregnant during treatment with REXULTI.
 - There is a pregnancy exposure registry for women who are exposed to REXULTI during pregnancy. If you become pregnant during treatment with 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. Talk to your healthcare provider about the best way to feed your baby during treatment with REXULTI.

Tell your healthcare provider about all the medicines you take, including prescription and 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 during treatment with REXULTI without first talking to your healthcare provider.

Know the medicines you take. Keep a list of them 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. Your healthcare provider may change your dose if needed. Do not change the dose or stop taking REXULTI without first talking to your healthcare provider.
- Take REXULTI 1 time each day with or without food.
- If you take too much REXULTI, call your healthcare provider or Poison Help Line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

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.
- Do not become too hot or dehydrated during treatment with REXULTI.
 - Do not exercise too much.
 - In hot weather, stay inside in a cool place if possible.
 - Stay out of the sun.
 - Do not wear too much clothing or heavy clothing.
 - Drink plenty of water.

What are the possible side effects of REXULTI?

REXULTI may cause serious side effects, including:

- **See “What is the most important information I should know about REXULTI?”**
- **Cerebrovascular problems, including stroke, in elderly people with dementia-related psychosis that can lead to death.**
- **Neuroleptic malignant syndrome (NMS) is a serious condition that can lead to death.** Call your healthcare provider or go to the nearest hospital emergency room right away if you have some or all of the following signs and symptoms of NMS:
 - high fever
 - stiff muscles
 - confusion
 - changes in your pulse, blood pressure, heart rate, and breathing
 - increased sweating

- **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) and diabetes.** Increases in blood sugar can happen in some people who take REXULTI. Extremely high blood sugar can lead to coma or death. Your healthcare provider should check your blood sugar before you start, or soon after you start REXULTI and then regularly during long term treatment with REXULTI.
Call your healthcare provider if you have any of these symptoms of high blood sugar during treatment with REXULTI:
 - feel very thirsty
 - feel very hungry
 - feel sick to your stomach
 - need to urinate more than usual
 - feel weak or tired
 - feel confused, or your breath smells fruity
 - **increased fat levels (cholesterol and triglycerides) in your blood.** Your healthcare provider should check the fat levels in your blood before you start, or soon after you start REXULTI, and then periodically during treatment with REXULTI.
 - **weight gain.** You and your healthcare provider should check your weight before you start and often during treatment with REXULTI.
- **Unusual and uncontrollable (compulsive) urges.** Some people taking REXULTI have had strong unusual urges, to gamble and gambling that cannot be controlled (compulsive gambling). Other compulsive urges include sexual urges, shopping, and eating or binge eating. If you or your family members notice that you are having new or unusual strong urges or behaviors, talk to your healthcare provider.
- **Low white blood cell count.** Your healthcare provider may do blood tests during the first few months of treatment with REXULTI.
- **Decreased blood pressure (orthostatic hypotension) and fainting.** You may feel dizzy, lightheaded, or pass out (faint) when you rise too quickly from a sitting or lying position.
- **Falls.** REXULTI may make you sleepy or dizzy, may cause a decrease in your blood pressure when changing position (orthostatic hypotension), and can slow your thinking and motor skills which may lead to falls that can cause fractures or other injuries.
- **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.
- **Sleepiness, drowsiness, feeling tired, difficulty thinking and doing normal activities.** See “What should I avoid while taking REXULTI?”

The most common side effects of REXULTI include weight gain, sleepiness, dizziness, common cold symptoms, and restlessness or feeling like you need to move (akathisia).

These are not all the possible side effects of REXULTI.

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. You can ask your pharmacist or healthcare provider for information about REXULTI that is written for health professionals.

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

For color: titanium dioxide, iron oxide, and ferrousferrous oxide

Manufactured by Otsuka Pharmaceutical Co., Ltd., Tokyo 101-8535, Japan

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

Marketed by Lundbeck, Deerfield, IL 60015 USA

©2023 For more information about REXULTI, go to www.REXULTI.com or call 1-800-441-6763.

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

Revised: 5/2023

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