



Discover a treatment for agitation that may happen with dementia due to Alzheimer's disease.

[FIND OUT MORE >](#)

INDICATION:

REXULTI is a prescription medicine used 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.

SELECT 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 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.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 14-15.





Actor portrayals

What is agitation that may happen with dementia due to Alzheimer's disease?

While it may sound like Alzheimer's dementia, the 2 conditions aren't the same and are diagnosed separately. Agitation that may happen with dementia due to Alzheimer's disease can cause your loved one to act out in ways you may not have seen before. The symptoms can be broken down into 3 categories: Restlessness, Verbal Aggression, and Physical Aggression—each with their own set of behaviors and challenges that you may recognize.

You're not alone in caring for a loved one.

Of the 6.7 million people 65 and older in the US with Alzheimer's dementia, multiple studies show that about half or more develop agitation that may happen with dementia due to Alzheimer's disease.

Keep track of the symptoms of agitation that may happen with dementia due to Alzheimer's disease.

Regardless of how few or many symptoms your loved one may have experienced, it's important to let their doctor know what you've noticed.



Restlessness

- Pacing/rocking
- Jumpiness
- Inappropriate social behavior/pointing
- Irritability
- Shakiness
- Repetitive mannerisms
- Wandering
- Hoarding



Verbal Aggression

- Screaming
- Swearing
- Complaining
- Constant requests for attention
- Being negative
- Emotional outbursts
- Strange noises (unwarranted laughter, crying)
- Inappropriate language (cursing, sexual advances)
- Repetitive questions and sentences



Physical Aggression

- Biting
- Hitting
- Kicking
- Hurting self and/or others
- Inappropriate physical behaviors (sexual advances, spitting, scratching, slamming doors)
- Destroying things
- Throwing things
- Resisting help



Actor portrayals



Actor portrayals

Nearly a decade of supporting patients

REXULTI has been prescribed over 6 million times for patients with a variety of conditions.

It's been helping patients with other conditions since 2015, and in May 2023, REXULTI was approved to help those with agitation that may happen with dementia due to Alzheimer's disease.

The only FDA-approved treatment for agitation that may happen with dementia due to Alzheimer's disease

Until recently, there hasn't been an FDA-approved medicine for agitation that may happen with dementia due to Alzheimer's disease, but REXULTI has changed that. REXULTI should not be used as an "as needed" treatment for this condition.

As a caregiver, helping your loved one can be difficult. But talking to their doctor is an important next step to help reduce their symptoms.

SELECT IMPORTANT SAFETY INFORMATION:

Do not take REXULTI if you are allergic to brexpiprazole or any of the ingredients in REXULTI.



Helping loved ones like yours

In clinical studies,* REXULTI helped patients achieve:

 Significant reduction in frequency of symptoms.

*REXULTI was studied in two 12-week clinical trials with patients aged 51-90 with agitation that may happen with dementia due to Alzheimer's disease. At the end of the 12 weeks, patients who took REXULTI experienced a greater improvement in their symptoms of agitation compared to those who took a placebo.

Individual results may vary.

An important part of your loved one's journey is working with their doctor to find what works for them.

With REXULTI, less frequent symptoms may be possible.

SELECT IMPORTANT SAFETY INFORMATION:

REXULTI may cause serious side effects, including:

- Cerebrovascular problems, including stroke, in elderly people with dementia-related psychosis that can lead to death.



Actor portrayals



Actor portrayals

Frequently asked questions

How should REXULTI be taken?

REXULTI is taken once daily, with or without food. It's important to talk to your loved one's pharmacist or healthcare provider if either of you have any questions about taking REXULTI.

- Have your loved one take REXULTI as their healthcare provider prescribed it.
- Do not change the dose or have your loved one stop taking REXULTI without first talking to their healthcare provider. Only their healthcare provider may change the dose if needed.
- **Your loved one should not take REXULTI if they are allergic to brexpiprazole or any of the ingredients in REXULTI.**
- If they take too much REXULTI, call your healthcare provider or the Poison Control Center at 1-800-222-1222 right away or go to the nearest hospital emergency room.

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

SELECT IMPORTANT SAFETY INFORMATION:

REXULTI may cause serious side effects, including: *(continued)*

- **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; changes in your pulse, blood pressure, heart rate, and breathing; stiff muscles; confusion; increased sweating.



FAQs continued

Can REXULTI be taken with other medications?

Tell your loved one's healthcare provider about all the medicines they take or have recently taken, 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 loved one's healthcare provider can tell you if it's safe for your loved one to take REXULTI with their other medicines. Do not start or stop any medicines during treatment with REXULTI without talking to their healthcare provider first.

REXULTI was studied in people who were also taking other medications, including those to help manage Alzheimer's disease.

SELECT IMPORTANT SAFETY INFORMATION:

REXULTI may cause serious side effects, including: *(continued)*

- **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.





FAQs continued

What are the side effects of REXULTI?

In clinical studies* at least 2% or more of people treated with REXULTI reported the following side effects more than those taking placebo (sugar pill):

	ALL REXULTI doses (1,† 2, and 3 mg)	Placebo (sugar pill) (503 people) (251 people)
Common cold symptoms	3%	2%
Urinary tract infections (UTIs)	3%	1%
Dizziness	3%	2%
Headache	8%	8%
Sleepiness	3%	1%
Insomnia	4%	3%

*REXULTI was studied in two 12-week clinical trials with patients aged 51-90 with agitation that may happen with dementia due to Alzheimer's disease. At the end of the 12 weeks, patients who took REXULTI experienced a greater improvement in their symptoms of agitation compared to those who took a placebo.

†1 mg once-a-day REXULTI dosage is not a recommended dosage for the treatment of agitation that may happen with dementia due to Alzheimer's disease.

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

Take note of any side effects your loved one experiences while on REXULTI and report them to their healthcare provider, especially if they are new, worsening, or worry you.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 14-15.



Actor portrayals

SELECT IMPORTANT SAFETY INFORMATION:

REXULTI may cause serious side effects, including: *(continued)*

- **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.



FAQs continued

Could REXULTI affect my loved one's blood sugar?

An increase in blood sugar (hyperglycemia) can happen in some people who take REXULTI. Extremely high blood sugar can lead to coma or death. Your loved one's healthcare provider should check their blood sugar before they start, or soon after they start REXULTI, and then regularly during long-term treatment with REXULTI.

Call your loved one's healthcare provider if they have any of these symptoms of high blood sugar while taking REXULTI: they feel very thirsty; feel very hungry; feel sick to their stomach; need to urinate more than usual; feel weak or tired; feel confused, or their breath smells fruity.

Will REXULTI affect my loved one's cholesterol?

An increase in the fat levels (cholesterol and triglycerides) in your loved one's blood may occur while taking REXULTI. Before starting on REXULTI, discuss with their healthcare provider if they have high levels of cholesterol, triglycerides, or LDL cholesterol, or low levels of HDL cholesterol.

Your loved one's healthcare provider should check the fat levels in their blood before they start, or soon after they start REXULTI, and then periodically during treatment with REXULTI.

During clinical trials for agitation that may happen with dementia due to Alzheimer's disease,* changes in total cholesterol, LDL cholesterol, and HDL cholesterol were similar in patients treated with REXULTI and patients treated with placebo.

Could REXULTI make my loved one feel sleepy or drowsy?

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

During clinical trials for agitation that may happen with dementia due to Alzheimer's disease,* sleepiness was reported in 3% of patients treated with REXULTI compared to 1% of patients treated with placebo.

*Two 12-week clinical trials. For more information about the clinical trials, see [page 5](#).

For more questions you may have about REXULTI, visit [REXULTI.com/aad/frequently-asked-questions](https://www.rexulti.com/aad/frequently-asked-questions).

SELECT IMPORTANT SAFETY INFORMATION:

REXULTI may cause serious side effects, including: *(continued)*

- **Problems with your metabolism such as:**
 - **high blood sugar (hyperglycemia) and diabetes.** *(continued)*

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

Tips for talking with the doctor

Everyone's journey is different. No matter where your loved one is on their path, here are some tips for talking to their doctor about agitation that may happen with dementia due to Alzheimer's disease:



Be clear and specific.

Say "She'll ask the same question five times in an hour. She does that several times a week," rather than "She seems worried and asks the same questions a lot." The difference, while it may seem small, is vital to help their treatment team understand the state of their condition.



Recognize body language cues.

Being aware of your loved one's body language is crucial and will allow you to notice shifts in their comfort and mood brought on by agitation that may happen with dementia due to Alzheimer's disease.



Keep a running list of what you notice.

Try keeping a list of symptoms you see your loved one experiencing, however frequent or infrequent. Note things like the time of day a symptom occurred or if there was a certain trigger you noticed. These details can be useful for their doctor to have a better understanding of their symptoms or situation.



As a caregiver, helping yourself helps your loved one too.

It can be quite difficult as a care partner. You may go through a wide range of emotions and challenges on a daily basis—which is understandable.

That's why it can be helpful to check in with yourself. Finding a healthy balance between caring for someone you love and caring for yourself can benefit your well-being.



Reach out to a local support group.

There are local and nationally sponsored support groups, both in person and online. You can also speak with a therapist who specializes in caregiver support.



Build a care team and utilize them.

Enlist family members and friends to increase your support network. When you need a hand or maybe just a break, see if one of them can step in—and be specific in your requests so they know exactly how to help.



Carve out time for yourself.

Socializing can make a big difference to help you find balance. Maybe it's a walk in the park or shopping with a friend. Simple outings or activities on a regular basis can help you reset and maintain your own well-being.



Actor portrayals



Elevmi™— an app for caregivers like you

Elevmi™ is a free app tailored for caregivers navigating the challenges of caring for a family member diagnosed with Alzheimer's disease.

Learn more at elevmi.com.

Elevmi is not specific to any prescription treatment.
Elevmi is a registered trademark of Otsuka Precision Health, Inc.

Many organizations are available to support those living with Alzheimer's and their caregivers. Here are a few that may help.



The Alzheimer's Foundation of America (AFA) is a nationwide organization that provides support, services, and education to those affected by Alzheimer's and related dementias. Services include a helpline (866-232-8484) staffed by licensed social workers. www.alzfdn.org



UsAgainstAlzheimer's works to promote earlier detection, diagnosis, and intervention, and to drive changes that matter most to caregivers and people living with Alzheimer's. www.usagainstalzheimer.org

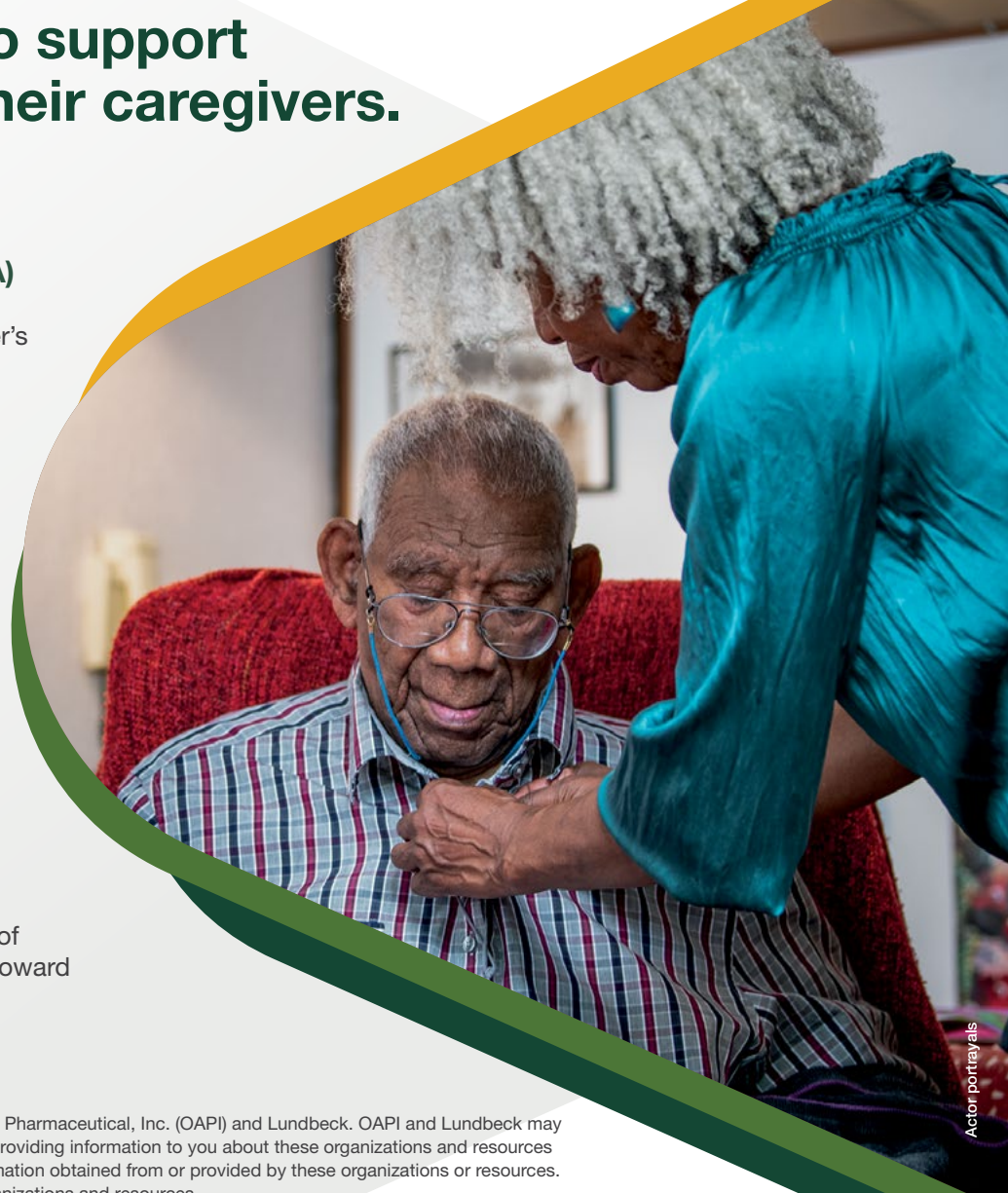


Alzheimer's Association is a worldwide organization founded on inclusivity and equality. They're committed to bringing education, resources, advocacy, and support to all those affected by Alzheimer's dementia and other related dementias. www.alz.org



Caregiver Action Network strives to help caregivers better understand a variety of symptoms that can accompany dementia and works toward improving their quality of life. www.caregiveraction.org

The organizations and resources listed are not affiliated with nor are they controlled or influenced by Otsuka America Pharmaceutical, Inc. (OAPI) and Lundbeck. OAPI and Lundbeck may have supported the important work of some of these organizations through sponsorships. OAPI and Lundbeck are providing information to you about these organizations and resources merely as a convenience, and OAPI and Lundbeck shall not be liable for any use of this information, or for any information obtained from or provided by these organizations or resources. OAPI and Lundbeck are not responsible for the consequences of your use of any information provided by these organizations and resources.



Actor portrayals

Paying for REXULTI[®] (brexpiprazole)

Want to know what your loved one's prescriptions may cost? Here's some helpful information.



Medicare

With Medicare, the out-of-pocket costs for REXULTI prescriptions average about \$21.37 per month.* Of course, out-of-pocket costs vary throughout the year depending on which phase of Part D your loved one is in.

Your loved one's costs could be less if they are eligible for the Social Security Administration's Extra Help Program. Visit www.ssa.gov/benefits/medicare/prescriptionhelp for more information and to see if your loved one qualifies.

Have questions about Medicare Part D? Go to NavigatingPartD.com.



Medicaid

With Medicaid, the cost of REXULTI averages about \$2.88 a month.* You may pay more or less depending on your state's formulary.

To find out if your loved one qualifies for Medicaid, or to learn more about co-payments in your state, visit www.medicicaid.gov/state-overviews/index.html.

It's a good idea to plan ahead by estimating annual drug costs and how much you'll pay for your loved one's medication throughout the year.



Have commercial insurance? Pay as little as \$0 to start.

If your loved one has been prescribed REXULTI and has commercial insurance, they may be eligible for the REXULTI Savings Card.

- Pay as little as \$0 for the first two months[†]
- Pay as little as \$5 per refill, even for 90-day prescriptions[‡]

If your loved one is prescribed a generic antidepressant, they may pay as little as \$0 for their prescription.

Get the REXULTI Savings Card now by texting **SAVE to 96747**.[§]

*Based on average patient price from January–December 2022.

[†]Offer not valid for cash-paying patients OR where drug is not covered by primary insurance. Additional Terms & Conditions apply. 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.

[‡]89% of REXULTI patients pay \$5 or less (Based on average patient price from Jan-Dec 2022).

[§]Message and data rates may apply. Message frequency varies. Text HELP for help and STOP to opt-out. Otsuka may use pharmacy information to provide refill reminders with your consent. Terms of Service: www.rexulti.com/savings-card-terms-conditions. Privacy Policy: <https://www.otsuka-us.com/privacy-policy>.

INDICATION and IMPORTANT SAFETY INFORMATION for REXULTI[®] (brexpiprazole)

INDICATION:

REXULTI is a prescription medicine used 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.

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 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.

Do not take REXULTI if you are allergic to brexpiprazole or any of the ingredients in REXULTI.

REXULTI may cause serious side effects, including:

- **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; changes in your pulse, blood pressure, heart rate, and breathing; stiff muscles; confusion; 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.

(continued on next page)

IMPORTANT SAFETY INFORMATION for REXULTI® (brexpiprazole)

(continued)

REXULTI may cause serious side effects, including: (continued)

- **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.** 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.
- **Difficulty swallowing** that can cause food or liquid to get into your lungs.
- **Sleepiness, drowsiness, feeling tired, difficulty thinking and doing normal activities.** 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 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.

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. For more information, ask your healthcare provider or pharmacist.

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).



Ask your loved one's doctor
if REXULTI may help.

For more information, visit [REXULTI.com](https://www.rexulti.com).

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

