

Medical Question

Does REXULTI® (brexpiprazole) cause weight gain when taken with an antidepressant (ADT) in patients with major depressive disorder (MDD)?

[pronunciation: REX-ul-TE]

Medical Response

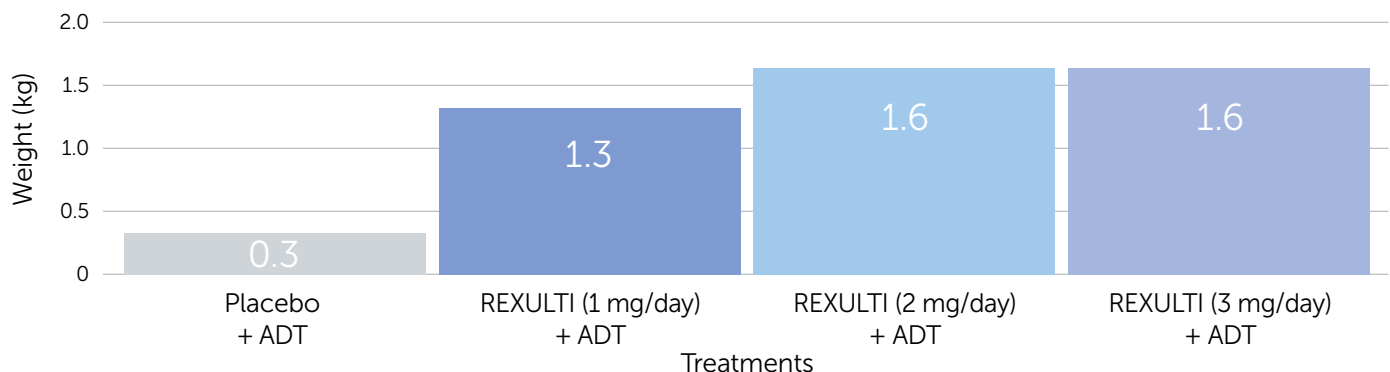
REXULTI may cause serious side effects, including weight gain.



In two 6-week clinical studies of adult patients with MDD:

- Of 643 patients taking REXULTI plus an ADT, 7% of patients saw an increase in body weight
- Of 411 patients receiving placebo plus an ADT, 2% of patients saw an increase in body weight

Average Weight Gain



In long-term MDD studies, the average weight gain seen with REXULTI plus an ADT was 2.9 kg at Week 26 and 3.1 kg at Week 52.

You and your healthcare provider should check your weight before you start and often during treatment with REXULTI.

See next page for more information on REXULTI.

ABBREVIATIONS: ADT = antidepressant; kg = kilogram;
MDD = major depressive disorder; mg = milligram
REFERENCE: REXULTI® (brexpiprazole) Prescribing Information.



More Important Information

What should I know about REXULTI?

REXULTI is a prescription medicine used with other antidepressant medicines to treat major depressive disorder (MDD) in adults and to treat schizophrenia in adults and children ages 13 years and older. It is not known if REXULTI is safe and effective in children with MDD or in children under 13 years of age with schizophrenia.

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. **Increased risk of suicidal thoughts and actions.** Antidepressant medicines may increase suicidal thoughts and actions in some children, adolescents, and young adults **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: thoughts about suicide or dying, new or worsening depression, feeling very agitated or restless, trouble sleeping (insomnia), acting aggressive, being angry, or violent, an extreme increase in activity or talking (mania), attempts to commit suicide, new or worsening anxiety, panic attacks, new or worsening irritability, acting on dangerous impulses, other unusual changes in behavior or mood.

What should I do with this information?

The information provided above is for informational purposes only and does not replace the advice provided by your healthcare provider. It is intended to answer your question about REXULTI but may not contain all the available information. You should not act upon the information without discussing it with your healthcare provider. Please speak with your healthcare provider, as they are in the best position to advise you about the use of the product and have access to the details of your medical history.

Where can I learn more about REXULTI?

For further information on the safe and effective use of REXULTI, please refer to the full Medication Guide, which can be accessed by clicking [here](#) or you can contact us at 1-800-441-6763. You may also speak to your healthcare provider if you have questions about REXULTI.

What should I do if I have any side effects?

Call your healthcare provider for medical advice about side effects. To report any possible side effects or product quality complaints about an Otsuka product, please call 1-800-438-9927 or contact the FDA directly at 1-800-FDA-1088.

