

FDA approves new drug for schizophrenia, major depression

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Medication can be used as an add-on therapy to antidepressants.

(HealthDay)—A new drug to treat schizophrenia and depression has been approved by the U.S. Food and Drug Administration.

Rexulti (brexpiprazole) tablets can be used to treat adults with [schizophrenia](#). The new drug can also be used as an add-on therapy to [antidepressant drugs](#) for adults with [major depression](#).

"Schizophrenia and [major depressive disorder](#) can be disabling and can greatly disrupt day-to-day activities," Dr. Mitchell Mathis, director of the Division of Psychiatry Products in the FDA's Center for Drug Evaluation and Research, said in an agency news release.

"Medications affect everyone differently so it is important to have a variety of treatment options available for patients with mental illnesses," he added.

The FDA's approval of Rexulti for treatment of schizophrenia is based on two six-week clinical trials with more than 1,300 people. People taking the drug had fewer symptoms of schizophrenia than those who took a placebo, the studies found.

Rexulti was also tested as an add-on therapy for major depression. For this treatment, researchers conducted two six-week clinical trials. The trials included more than 1,000 patients whose symptoms were not adequately treated by taking an antidepressant alone. Those who took Rexulti and an antidepressant had fewer symptoms of depression than those who took a placebo and an antidepressant, the FDA said.

Weight gain and a sense of restlessness were the most common side effects reported by patients taking Rexulti. The drug is made by Otsuka Pharmaceutical Company Ltd. in Japan.

Like other [schizophrenia drugs](#), Rexulti has a boxed warning about an increased risk of death associated with unapproved use of the drugs to treat behavioral problems in people with dementia-related psychosis.

The boxed warning also cautions about an increased risk of [suicidal thoughts](#) and behavior in children, teens and young adults taking antidepressants. People taking the drug should be monitored for the start or worsening of suicidal thoughts and behavior, the FDA said.

More information: The U.S. National Institute of Mental Health has more about [schizophrenia](#).

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