

FDA approves new drug for schizophrenia, bipolar disorder

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Vraylar is an atypical antipsychotic taken once a day.

(HealthDay)—A new antipsychotic drug to treat schizophrenia and bipolar disorder in adults has been approved by the U.S. Food and Drug Administration.

The drug, Vraylar (cariprazine), is a capsule taken once a day.

"Schizophrenia and [bipolar disorder](#) can be disabling and can greatly interfere with 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.

"It is important to have a variety of treatment options available to patients with mental illnesses so that treatment plans can be tailored to meet a patient's individual needs," Mathis said.

Schizophrenia, a chronic and disabling brain disorder that usually develops in early adulthood, occurs in 1 percent of the general population, according to the U.S. National Institute of Mental Health. People with the condition often see or hear things that are not there. They are also withdrawn or paranoid, believing others are trying to read their mind or control their thoughts.

Vraylar belongs to a class of drugs known as atypical antipsychotics. Others in this group include Abilify (aripiprazole), Seroquel (quetiapine) and Risperdal (risperidone).

The drug's effectiveness in treating schizophrenia was tested among more than 1,750 patients in three six-week clinical trials. It was shown to reduce schizophrenia symptoms compared to the placebo. The drug's maker, Forest Labs, and distributor, Actavis Pharma, are based in New Jersey.

The most commonly reported side effects in the schizophrenia trials were tremor, slurred speech and involuntary muscle movements.

Bipolar disorder, also known as manic-depressive illness, leads to dramatic mood swings or shifts in energy and activity levels. People with bipolar disorder have alternating episodes of depression and mania, or "highs," characterized by irritability, increased activity, restlessness, impulsive behavior and racing thoughts. Almost 3 percent of U.S. adults have bipolar disorder, the [mental health](#) institute says.

In three three-week trials involving more than 1,000 bipolar patients, Vraylar reduced disorder symptoms, the FDA said.

The most common drug-related side effects in the bipolar disorder trial included tremor, slurred speech, an urge to move (akathisia), indigestion, vomiting, drowsiness and restlessness.

All FDA-approved drugs for [schizophrenia](#) and bipolar disorder must carry a black box warning indicating an increased risk of death if these drugs are used by older people with dementia-related psychosis, the agency noted.

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

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