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Vraylar (cariprazine) capsules now approved by FDA to treat schizophrenia, bipolar disorder in adults

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The U.S. Food and Drug Administration today approved Vraylar (cariprazine) capsules to treat schizophrenia and bipolar disorder in adults.

"Schizophrenia and bipolar disorder can be disabling and can greatly interfere with day-to-day activities," said Mitchell Mathis, M.D., director of the Division of Psychiatry Products in the FDA's Center for Drug Evaluation and Research. "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."

Schizophrenia is a chronic, severe and disabling brain disorder affecting about one percent of Americans. Typically, symptoms are first seen in adults younger than 30 years of age and include hearing voices or seeing things that are not there, believing other people are reading their minds or controlling their thoughts, and being suspicious or withdrawn.

Bipolar disorder, also known as manic-depressive illness, is another brain disorder that causes unusual shifts in mood, energy, activity levels and the ability to carry out day-to-day tasks. The symptoms of bipolar disorder include alternating periods of depression and high, irritable mood, increased activity and restlessness, racing thoughts, talking fast, impulsive behavior and a decreased need for sleep.

The efficacy of Vraylar in treating schizophrenia was demonstrated in 1,754 participants in three six-week clinical trials. In each of the trials, Vraylar was shown to reduce the symptoms of schizophrenia compared to placebo.

The efficacy of Vraylar in treating bipolar disorder was shown in three three-week clinical trials of 1,037 participants. Vraylar was shown to reduce symptoms of bipolar disorder in each of the trials.

Vraylar and all other FDA-approved drugs used to treat schizophrenia and bipolar disorder have a Boxed Warning alerting health care professionals about an increased risk of death associated with the use of these drugs in older people with dementia-related psychosis. Neither Vraylar nor any other drug in this class is approved to treat such patients.

The most common side effects reported by participants receiving Vraylar in the clinical trials for schizophrenia were extrapyramidal symptoms, such as tremor, slurred speech, and involuntary muscle movements. The most common side effects reported by trial participants receiving Vraylar for bipolar disorder were extrapyramidal symptoms, the urge to move (akathisia), indigestion (dyspepsia), vomiting, drowsiness (somnolence) and restlessness.

Vraylar is manufactured by Forest Laboratories LLC of Jersey City, New Jersey and distributed by Actavis Pharma Inc. of Parsippany, New Jersey.

Source:
http://www.fda.gov
