

Vraylar[®] (cariprazine) – New indication

- On May 28, 2019, [Allergan and Gedeon Richter announced](#) the FDA approval of [Vraylar \(cariprazine\)](#), for treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adults.
- Vraylar is also approved in adults for the treatment of schizophrenia and acute treatment of manic or mixed episodes associated with bipolar I disorder.
- There are nearly 11 million adults in the U.S. living with bipolar disorder, a condition that causes periods of severe changes in mood, energy, and activity levels.
 - Bipolar depression refers to the depressive episodes of bipolar I disorder. People living with bipolar I disorder can have manic and depressive episodes, as well as mixed episodes that feature both manic and depressive symptoms at the same time.
 - Depressive symptoms are three times more prevalent than manic symptoms.
- The approval of Vraylar's new indication was based on one 8-week and two 6-week placebo-controlled studies in patients with depressive episodes associated with bipolar I disorder. In each study, the primary endpoint was change from baseline in Montgomery-Åsberg Depression Rating Scale (MADRS) total score at the end of week 6.
 - In the 8-week study (N = 571), Vraylar 1.5 mg daily was superior to placebo at the end of week 6 on the MADRS total score (difference -4.0; 95% CI: -6.3, -1.6).
 - In the first 6-week study (N = 474), Vraylar 1.5 mg and 3 mg daily were superior to placebo at the end of week 6 on the MADRS total score (Vraylar 1.5 mg: difference -2.5; 95% CI: -4.6, -0.4; Vraylar 3 mg: difference -3.0; 95% CI: -5.1, -0.9).
 - In the second 6-week study (N = 478), Vraylar 1.5 mg daily was superior to placebo at the end of week 6 on the MADRS total score (difference -2.5; 95% CI: -4.6, -0.4).
- Vraylar carries a boxed warning for increased mortality in elderly patients with dementia-related psychosis and suicidal thoughts and behaviors.
- The most common adverse reactions (≥ 5% and at least twice the rate of placebo) with Vraylar use in bipolar depression were nausea, akathisia, restlessness, and extrapyramidal symptoms.
- The recommended starting dose of Vraylar is 1.5 mg once daily for treatment of bipolar depression. Depending upon clinical response and tolerability, the dosage can be increased to 3 mg once daily on day 15. The maximum recommended dosage is 3 mg once daily.
 - Refer to the Vraylar drug label for dosing for its other indications.