



This summary contains important risk information about VRAYLAR (cariprazine). The information provided here is not comprehensive, and is not meant to take the place of your healthcare provider's instructions. To learn more, talk about VRAYLAR with your healthcare provider or pharmacist. The FDA-approved product labeling can be found at [www.vraylar.com](http://www.vraylar.com) or call 1-800-678-1605.

## Prescription Drug Facts for VRAYLAR™

### Uses

- Acute treatment of manic or mixed episodes of bipolar I disorder in adults.
- Treatment of schizophrenia in adults.

It is not known if VRAYLAR is safe and effective in children.

### Warnings

**WARNING: INCREASED RISK OF DEATH IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS**  
Elderly people with dementia-related psychosis (having lost touch with reality due to confusion and memory loss) taking antipsychotic drugs are at an increased risk of death. VRAYLAR is not approved for treating people with dementia-related psychosis.

- **Stroke**, which can be fatal, in elderly people with dementia.
- **Neuroleptic malignant syndrome (NMS)**. Call your healthcare provider right away if you have high fever; stiff muscles; confusion; changes in pulse, heart rate, or blood pressure; or sweating. These can be symptoms of a rare but potentially fatal side effect called NMS. VRAYLAR should be stopped if you have NMS.
- **Tardive dyskinesia (TD)**. Tell your healthcare provider if you cannot control the movements of your face, tongue, or other body parts. These could be signs of a serious and sometimes permanent side effect called TD. The risk of developing TD and the chance that it will become permanent are thought to increase the longer the person takes the medicine and the more medicine a person takes over time. TD can develop even after a person has been taking the medicine for a short time at low doses. TD may partially or completely go away if you stop taking VRAYLAR. TD may also start after you stop taking VRAYLAR.
- **Late-occurring side effects**. VRAYLAR stays in the body for several weeks, even after you stop taking it, which could affect the timing of when you may experience side effects. Tell your healthcare provider if you have side effects (eg, uncontrolled movements of the body and face, muscle stiffness, or feelings of restlessness) as these may occur several weeks after starting or increasing the dose of VRAYLAR.
- **Problems with your metabolism, such as:**
  - **High blood sugar and diabetes**. If you have diabetes or risk factors for diabetes (eg, being overweight or family history of diabetes), your blood sugar should be tested before you start VRAYLAR and regularly during treatment. Complications of diabetes can be serious and even life-threatening. Tell your healthcare provider if you have symptoms such as feeling very thirsty or very hungry, urinating more than usual, or feeling weak.
  - **Increased blood cholesterol or triglycerides**. Your healthcare provider should check your cholesterol and triglyceride levels before and during treatment.
  - **Weight gain** has been reported with VRAYLAR. Your healthcare provider should check your weight before and regularly during treatment.
- **Low white blood cell (WBC) count**. Low WBC counts have been reported with antipsychotic drugs, including VRAYLAR. This may increase your risk of infection. Very low WBC counts, which can be fatal, have been reported with other antipsychotic drugs.
- **Orthostatic hypotension (decreased blood pressure)**. You may feel light-headed or faint when you rise too quickly from a sitting or lying position due to a sudden change in heart rate and blood pressure. This may occur especially early in treatment and also when restarting treatment or increasing the dose. Your healthcare provider may monitor your heart rate and blood pressure if you are at risk of decreased blood pressure or if you have heart disease or disease affecting blood supply to the brain.
- **Seizures** may occur with VRAYLAR and other antipsychotic drugs. The risk is greatest if you have a history of seizures or conditions that could lead to seizures, which may be more common in older people.
- **Impaired judgment, thinking and motor skills**. Do not drive or use dangerous machinery until you know how VRAYLAR affects you. VRAYLAR may make you drowsy.
- **Increased body temperature**. VRAYLAR may make you more sensitive to heat. You may have trouble cooling off. Be careful when exercising or when doing things likely to cause dehydration or make you warm.
- **Difficulty swallowing** has been associated with VRAYLAR and other antipsychotic drugs.

### Do NOT use if you

- are allergic to cariprazine or any of the ingredients in VRAYLAR. Get emergency medical help if you are having an allergic reaction (eg, rash, itching, hives, swelling of the tongue, lip, face or throat).

## Prescription Drug Facts for VRAYLAR™ (continued)

### **Tell your healthcare provider before use if you have or have had**

- diabetes or high blood sugar in you or your family
- high levels of total cholesterol, triglycerides, or LDL-cholesterol; or low levels of HDL-cholesterol
- seizures or conditions that increase your risk for seizures
- low or high blood pressure
- low white blood cell count

### **Ask your healthcare provider before use if you are taking**

- any prescription medicines, over-the-counter medicines, herbal supplements or vitamins. VRAYLAR and certain medicines, such as some antibiotics (eg, rifampin), antifungal medications (eg, itraconazole, ketoconazole), and anti-seizure medications (eg, carbamazepine) may affect each other.

### **When using this product you may have**

- uncontrolled movements of the body and face
- muscle stiffness
- indigestion
- vomiting
- sleepiness
- restlessness

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**If pregnant or breastfeeding**, ask your healthcare provider before use. Tell your healthcare provider if you are pregnant, or if you plan to become pregnant. Using VRAYLAR in the third trimester may cause uncontrolled movements of the body and face, muscle stiffness, or feelings of restlessness and/or withdrawal symptoms in newborn babies. A special program (National Pregnancy Registry for Atypical Antipsychotics) collects information on the safety of antipsychotic drugs, including VRAYLAR, during pregnancy. For information, contact the program at 1-866-961-2388 or visit <http://www.womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/>.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

### **Other information**

- Rx only
- 1.5 mg, 3 mg, 4.5 mg, and 6 mg capsules
- Last updated: 09/2015



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Based on PI CAR37687-F-09/15

CAR44393 02/16