Doctor Discussion Guide

Communicating with your doctor is an important part of your treatment and a great way to make sure you get the best care possible. But it’s not always easy to know where to begin the conversation about your treatment.

We put together this quick and easy set of questions to help you get started.

Please print this document or save it to your mobile device. Then bring it to your next doctor appointment to discuss whether VRAYLAR® (cariprazine) may be right for your treatment plan.

How might VRAYLAR help to treat the manic or mixed episodes of my bipolar I disorder?

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When might VRAYLAR start to work for me?

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Will using VRAYLAR mean adding to my treatment plan or changing treatment plans?

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What possible side effects should I know about?

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Will VRAYLAR make me feel sleepy or drowsy?

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Will VRAYLAR make me gain weight?

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Do you think VRAYLAR could be right for me?

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INDICATION AND USAGE

VRAYLAR® is approved for the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.

IMPORTANT RISK INFORMATION

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.

Please see additional Important Risk Information on the following pages and Prescription Drug Facts, including Boxed Warning, for VRAYLAR.
What is the most important information I should know about VRAYLAR® (cariprazine)?

VRAYLAR may cause serious side effects, including:

- **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. Risk of developing TD and the chance that it will become permanent are thought to increase the longer a 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 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**: Weight gain has been reported with VRAYLAR. Your healthcare provider should check your weight before and regularly during treatment.
- **Low white blood cell count**: Low white blood cell counts have been reported with antipsychotic drugs, including VRAYLAR. This may increase your risk of infection. Very low white blood cell counts, which can be fatal, have been reported with other antipsychotics.
- **Decreased blood pressure**: You may feel lightheaded or faint when you rise too quickly from a sitting or lying position.
- **Falls**: VRAYLAR may increase risk of falls, which could cause fractures or other injuries.
- **Seizures**
- **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**: VRAYLAR and medicines like it have been associated with difficulty swallowing.

Who should not take VRAYLAR?

Do not take VRAYLAR if you are allergic to any of its ingredients. Get emergency medical help if you are having an allergic reaction (eg, rash, itching, hives, swelling of the tongue, lip, face, or throat).

What should I tell my healthcare provider before taking VRAYLAR?

Tell your healthcare provider about any medical conditions and 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

Please see additional Important Risk Information on the following page and Prescription Drug Facts, including Boxed Warning, for VRAYLAR.
IMPORTANT RISK INFORMATION: (continued)

What should I tell my healthcare provider before taking VRAYLAR? (continued)

Tell your healthcare provider if you are pregnant, or if you plan to become pregnant. Using VRAYLAR® (cariprazine) 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 http://www.womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/.

Tell your healthcare provider about all medicines that you take or have recently taken, including prescriptions, over-the-counter medicines, and supplements. VRAYLAR may affect the way other medicines work, and other medicines may affect how VRAYLAR works.

What are the most common side effects of VRAYLAR?

• The most common side effects were uncontrolled movements of the body and face, muscle stiffness, vomiting, indigestion, sleepiness, and restlessness.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all possible side effects of VRAYLAR.

Please see additional Important Risk Information on previous pages and Prescription Drug Facts, including Boxed Warning, for VRAYLAR.