

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?

When might VRAYLAR start to work for me?

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

What possible side effects should I know about?

Will VRAYLAR make me feel sleepy or drowsy?

Will VRAYLAR make me gain weight?

Do you think VRAYLAR could be right for me?

INDICATION AND USAGE

VRAYLAR[®] is approved in adults to treat depressive episodes (bipolar depression) and for the short-term treatment of manic or mixed episodes that happen with bipolar I disorder.

IMPORTANT RISK INFORMATION

What is the most important information I should know about VRAYLAR?

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.

Antidepressants may increase suicidal thoughts or actions in some children and young adults within the first few months of treatment and when the dose is changed. Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Patients on antidepressants and their families or caregivers should watch for new or worsening depression symptoms, especially sudden changes in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant is started or when the dose is changed. Report any change in these symptoms immediately to the doctor.

Please see additional Important Risk Information on the following pages and [Prescription Drug Facts](#), including Boxed Warnings, for VRAYLAR.

IMPORTANT RISK INFORMATION: (continued)

What is the most important information I should know about VRAYLAR® (cariprazine)?

VRAYLAR may cause serious side effects, including:

- **Stroke (cerebrovascular problems) in elderly people with dementia-related psychosis that can lead to death**
- **Neuroleptic malignant syndrome (NMS):** Call your healthcare provider right away if you have high fever, stiff muscles, confusion, increased sweating, or changes in breathing, heart rate, and blood pressure. These can be symptoms of a rare but potentially fatal side effect called NMS. VRAYLAR should be stopped if you have NMS
- **Uncontrolled body movements (tardive dyskinesia or 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 your body for a long time. Some side effects may not happen right away and can start a few weeks after starting VRAYLAR, or if your dose increases. Your healthcare provider should monitor you for side effects for several weeks after starting or increasing dose of VRAYLAR
- **Problems with your metabolism, such as:**
 - **High blood sugar and diabetes:** Increases in blood sugar can happen in some people who take VRAYLAR. Complications of diabetes can be serious and even life threatening. Your healthcare provider should check your blood sugar before or soon after starting VRAYLAR and regularly during treatment. Tell your healthcare provider if you have symptoms such as feeling very thirsty, very hungry, or sick to your stomach, urinating more than usual, feeling weak, tired, confused, or your breath smells fruity
 - **Increased fat levels (cholesterol and triglycerides) in your blood:** Your healthcare provider should check fat levels in your blood before or soon after starting VRAYLAR and during treatment
 - **Weight gain:** Weight gain has been reported with VRAYLAR. You and 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. Your healthcare provider may do blood tests during the first few months of treatment with VRAYLAR
- **Decreased blood pressure (orthostatic hypotension):** You may feel lightheaded or faint when you rise too quickly from a sitting or lying position
- **Falls:** VRAYLAR may make you sleepy or dizzy, may cause a decrease in blood pressure when changing position (orthostatic hypotension), and can slow thinking and motor skills, which may lead to falls that can cause fractures or other injuries
- **Seizures (convulsions)**
- **Impaired judgment, thinking, and motor skills:** Do NOT drive, operate machinery, or do other dangerous activities until you know how VRAYLAR affects you. VRAYLAR may make you drowsy
- **Increased body temperature:** Do not become too hot or dehydrated during VRAYLAR treatment. Do not exercise too much. In hot weather, stay inside in a cool place if possible. Stay out of the sun. Do not wear too much clothing or heavy clothing. Drink plenty of water
- **Difficulty swallowing** that can cause food or liquid to get into your lungs

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 heart problems or a stroke
- have or have had low or high blood pressure
- have or have had diabetes or high blood sugar in you or your family
- have or have had high levels of total cholesterol, LDL-cholesterol, or triglycerides; or low levels of HDL-cholesterol
- have or have had seizures (convulsions)
- have or have had kidney or liver problems
- have or have had low white blood cell count
- are pregnant or plan to become pregnant. VRAYLAR may harm your unborn baby. 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. If you become pregnant during treatment, talk to your healthcare provider about registering with the National Pregnancy Registry for Atypical Antipsychotics at 1-866-961-2388 or <http://www.womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/>.
- are breastfeeding or plan to breastfeed. It is not known if VRAYLAR passes into breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with VRAYLAR

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IMPORTANT RISK INFORMATION: (continued)

What should I tell my healthcare provider before taking VRAYLAR?

Tell your healthcare provider about all medicines that you take, including prescriptions, over-the-counter medicines, vitamins, and supplements. VRAYLAR may affect the way other medicines work, and other medicines may affect how VRAYLAR works. Do not start or stop any medicines while taking VRAYLAR without talking to your healthcare provider.

What are the most common side effects of VRAYLAR?

- The most common side effects include difficulty moving or slow movements, tremors, uncontrolled body movements, restlessness and feeling like you need to move around, sleepiness, nausea, vomiting, and indigestion.

These are not all possible side effects of VRAYLAR.

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