A bit about bipolar disorder

People diagnosed with bipolar disorder have periods called "mood episodes," which are severe changes from a person's typical mood. Mood episodes can be manic, depressive, or mixed. For example, people experiencing an episode of mania may describe their symptoms as feeling overly joyful or energetic, while those having a mixed episode have symptoms of both mania and depression at the same time.

How VRAYLAR can help

VRAYLAR (cariprazine) is a once-a-day pill, taken with or without food for the acute treatment of manic or mixed episodes of bipolar disorder.

In clinical studies, VRAYLAR was proven to help manage the overall manic symptoms of bipolar disorder.

You're not alone in this

In a given year, bipolar disorder affects nearly 6.1 million adults in the United States.

Visit AboutVraylar.com to read more

Other steps you can take:

Know your symptoms:

Not everyone with bipolar disorder experiences the same symptoms. Write down your moods, symptoms, and triggers so you can keep track of how your condition affects you personally.

Know your warning signs:

If you don't already know your warning signs, write down the things that happen to you in a given week—thoughts, feelings, and activities—so you can notice any small changes in your behavior. If you catch these changes early on, you may be able to help prevent an episode by contacting your doctor.

Make healthy choices:

Eating right, getting enough sleep, practicing yoga or meditation, and engaging in healthy levels of exercise can help reduce stress that can cause symptoms. Find what works for you and make it a habit.

Take your medication:

If left untreated, bipolar disorder can become dangerous to you or your loved ones. It's important to take your medicine as prescribed, even when you're feeling better.

Talk to someone:

Find someone to talk about what you're going through. Whether it's a therapist, a support group, or even a trusted friend or family member, it can help to have someone to lean on for encouragement.

Have a plan:

Talk to your doctor about what to do in case of an episode. Keep instructions in your wallet along with medical and contact information so you're always prepared.

Please see additional Important Risk Information on the following page and Prescription Drug Facts for VRAYLAR.

INDICATION AND USAGE

VRAYLAR (cariprazine) is approved for the acute treatment of manic or mixed episodes associated with bipolar 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.

There is no known cure for bipolar disorder, but there are ways to manage your manic symptoms. While medication can be a great first step in managing your condition, there are additional things you can do that may help you stay in control.

Please see additional Important Risk Information on the following page and Prescription Drug Facts for VRAYLAR.
IMPORTANT RISK INFORMATION

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

VRAYLAR may cause serious side effects, including:

- Stroke (which can be fatal in elderly people with dementia)
- Neuropsychiatric 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 NMS 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

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

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

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 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 1-866-961-2360 or http://www.evergreenhealth.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, including Boxed Warning on previous page, and Prescription Drug Facts for VRAYLAR.

Resources for more information and support:

National Alliance on Mental Illness (NAMI)
NAMI is the nation’s largest grassroots mental health organization dedicated to building better lives for the millions of Americans affected by mental illness.
www.nami.org | 1-800-950-NAMI (6264)

National Institute of Mental Health (NIMH)
The mission of NIMH is to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure.
www.nimh.nih.gov | 1-866-615-6464

Mental Health America (MHA)
MHA is the nation’s leading community-based nonprofit dedicated to helping all Americans achieve wellness by living mentally healthier lives.
www.mhanational.org | 1-800-989-6642

US Department of Health and Human Services
MentalHealth.gov provides one-stop access to U.S. government mental health and mental health problems information.
www.mentalhealth.gov

American Foundation for Suicide Prevention (AFSP)
AFSP is the leader in the fight against suicide. AFSP funds research, creates educational programs, advocates for public policies, and supports suicide loss.
www.afsp.org | 1-888-333-AFSP (2377)

Depression and Bipolar Support Alliance (DBSA)
DBSA provides hope, help, and support to education and improve the lives of people who have mood disorders.
www.dbsalliance.org | 1-800-826-3632

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

VRAYLAR may cause serious side effects, including:

• Strokes (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 symptoms may be part 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 in the longer a person takes the medicine and in the higher the dose a person takes. 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
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  - 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 your 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, lips, face, or throat).

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Tell your healthcare provider about any medical conditions and if you have or have had:

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• Seizures or conditions that increase your risk for seizures
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