



Vraylar

(cariprazine) capsules

1.5mg•3mg•4.5mg•6mg

**You are
greater
than your
bipolar I.**

**Ask your provider
if VRAYLAR can
help control your
bipolar I symptoms.**

VRAYLAR® is a prescription medication approved in adults to treat bipolar I 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 medicines like VRAYLAR are at an increased risk of death. VRAYLAR is not approved for treating patients 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 Important Risk Information throughout and Prescription Drug Facts, including Boxed Warnings, enclosed within this brochure.

What is bipolar I disorder?

Bipolar I disorder is a condition that causes periods of severe changes in mood, energy levels, and ability to carry out everyday tasks.

Medical researchers believe that it can result from many factors, including an imbalance of certain chemicals in the brain called neurotransmitters, which may be too high or too low.



IMPORTANT RISK INFORMATION (continued)

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 or go to the nearest hospital emergency room 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

Who has bipolar I disorder?

While anyone can develop bipolar I disorder, it often starts in the late teen or early adult years and is often misdiagnosed at least once.

Bipolar I disorder often runs in families. If you have a family history of bipolar I disorder, be sure to let your healthcare provider know.



You're not alone

About 2.5 million people in the US will develop bipolar I disorder at some point during their lives.* Some may never receive the correct diagnosis or treatment.

*Calculations are based on a 1% estimated lifetime prevalence and the estimated population of US residents in July 2019.

Living with bipolar I disorder

Experiencing the intense emotional highs and lows that bipolar I brings can lead to relationship issues, substance abuse, and difficulty at work or school.

Finding a treatment option that works for you can be an essential first step in managing your mood swings. In addition to medication, lifestyle changes, including getting restful sleep and healthier eating, can help to reduce symptoms.

IMPORTANT RISK INFORMATION (continued)

VRAYLAR may cause serious side effects, including:

- **Uncontrolled body movements (tardive dyskinesia or TD):** VRAYLAR may cause movements that you cannot control in your face, tongue, or other body parts. Tardive dyskinesia may not go away, even if you stop taking VRAYLAR. Tardive dyskinesia may also start after you stop taking VRAYLAR

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Why VRAYLAR?

VRAYLAR® provides full-spectrum relief for all bipolar I symptoms in depressive and short-term manic or mixed episodes in adults with one pill, once a day.



Helps reduce the symptoms related to depressive, acute manic, and mixed episodes associated with bipolar I disorder**



Was proven effective in treating bipolar I episodes across 6 studies

- at 3 weeks in 3 manic/mixed episodes studies
- at 6 weeks in 3 bipolar I depression studies



Is a once-daily pill that can be taken with or without food



Has been prescribed to over 400,000 people since 2016*

*Individual response to therapy may vary.

**VRAYLAR was not studied to measure symptoms individually.

*IMS Total Patient Tracker 2020.

IMPORTANT RISK INFORMATION (continued)

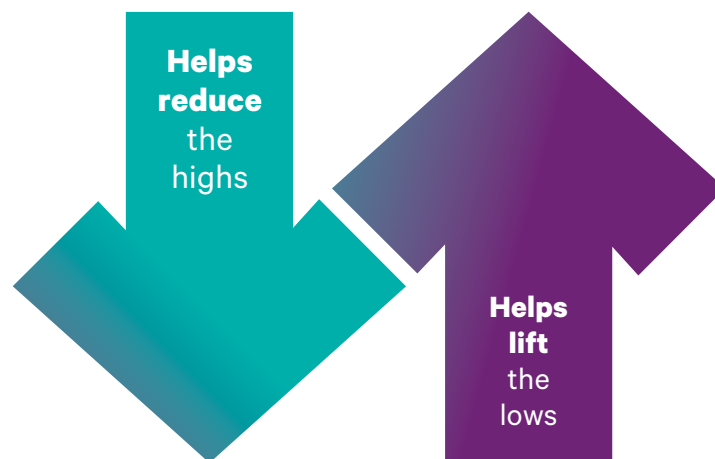
VRAYLAR may cause serious side effects, including:

- **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

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How VRAYLAR may work

It is thought that VRAYLAR helps regulate chemicals in the brain such as serotonin and dopamine. However, the exact way VRAYLAR works is unknown.



The highs

In a manic episode, it is thought that your chemical levels may be too high. VRAYLAR is thought to help decrease the brain receptors' response to these chemicals.

The lows

In a depressive episode, it is thought that your chemical levels may be too low. VRAYLAR is thought to help increase the brain receptors' response to these chemicals.



Full-spectrum relief for all bipolar I symptoms
Bipolar I Depression / Acute Mixed Episodes / Acute Mania

IMPORTANT RISK INFORMATION (continued)

VRAYLAR may cause serious side effects, including:

- **Problems with your metabolism, such as:**
 - **High blood sugar and diabetes:** Increases in blood sugar can happen in some people who take VRAYLAR. Extremely high blood sugar can lead to coma or death. 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

Sharing all your symptoms can help you take control.

To help your healthcare provider determine if you have bipolar I disorder, review some of the symptoms below. It also can be helpful to keep a journal of your mood shifts (extreme highs and lows), which you can discuss with your healthcare provider.

Check off all the DEPRESSIVE SYMPTOMS (also referred to as LOWS) that you've experienced for at least 2 weeks.

- Feeling very down or sad
- Sleeping too much or too little
- Having trouble sleeping
- Feeling like you can't enjoy anything
- Feeling worried and empty
- Having trouble concentrating
- Forgetting things a lot
- Changes in appetite or weight
- Feeling tired or slowed down
- Having little to no interest or pleasure in your hobbies
- Thinking about death or suicide

IMPORTANT RISK INFORMATION (continued)

VRAYLAR may cause serious side effects, including:

- **Problems with your metabolism, such as (continued):**
 - **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

Please see Important Risk Information throughout and Prescription Drug Facts, including Boxed Warnings, enclosed within this brochure.

Check off all the MANIC SYMPTOMS (also referred to as HIGHS) that you've experienced for at least 1 week.

- Having higher than usual energy levels
- Feeling jumpy or wired
- Not feeling tired or needing little sleep
- Becoming more active than usual
- Talking really fast about a lot of different things
- Becoming agitated, irritable, or touchy
- Feeling like your thoughts are coming very fast
- Thinking you can do a lot of things at once
- Behaving impulsively
- Feeling overconfident in your abilities

Check off all the MIXED-EPISODE SYMPTOMS (also referred to as HIGHS AND LOWS) that you've experienced at the same time.

- Feeling exhausted and overly anxious at the same time
- Having too much energy while feeling very sad
- Being talkative while pessimistic
- Behaving impulsively while feeling exhausted

The information contained herein is provided for informational purposes only and is not intended to replace a discussion with a healthcare provider. All decisions regarding patient care must be made with a healthcare provider and consider the unique characteristics of each patient.

IMPORTANT RISK INFORMATION (continued)

VRAYLAR may cause serious side effects, including:

- **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

A guide to help talk to your healthcare provider about VRAYLAR.

If you have frequent mood swings or you've been diagnosed with bipolar I ask your healthcare provider:

- 1** What does it mean if I have a family history of bipolar I?
- 2** What if I've failed on multiple antidepressants or have had sudden changes in mood or activity while taking an antidepressant?
- 3** How effective is VRAYLAR for bipolar I disorder?
- 4** How might VRAYLAR reduce the severity of my bipolar I?
- 5** How might VRAYLAR improve the symptoms of my bipolar I depression?
- 6** How might VRAYLAR improve the symptoms related to my manic episodes?

IMPORTANT RISK INFORMATION (continued)

VRAYLAR may cause serious side effects, including:

- **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

Discuss your symptoms and how you've tried to manage them.

My current symptoms are:

I've tried other ways to manage my symptoms; they are:

I've made some lifestyle changes to balance out my mood swings; they are:

Some of my most common triggers are:

IMPORTANT RISK INFORMATION (continued)

VRAYLAR may cause serious side effects, including:

- **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

Please see Important Risk Information throughout and Prescription Drug Facts, including Boxed Warnings, enclosed within this brochure.

Simple lifestyle changes that may help you manage your condition.



Talk it out

Whether it is a healthcare provider, therapist, family member, or a friend, it's good to have someone to talk to. Make a list of people you can call on short notice.



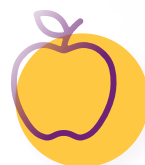
Involve family or friends

The people closest to you can be helpful when describing your symptoms. Consider bringing a family member or close friend to your next appointment.



Stick to the plan

It is important to take your medication as prescribed. Don't stop taking your medication without first discussing it with your healthcare provider. Discuss any medication changes with your healthcare provider first.



Make healthy a habit

Eating right, exercising, and getting enough sleep may help to reduce the stress that can trigger bipolar I symptoms.

IMPORTANT RISK INFORMATION (continued)

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

Please see Important Risk Information throughout and Prescription Drug Facts, including Boxed Warnings, enclosed within this brochure.

You are greater than your bipolar I.



Every journey with bipolar I is unique, every triumph over stigma leads to hope, and everyone is a work in progress. No matter where you are on your journey, remember that you are greater than your bipolar I disorder.

Surrounding yourself with people who care, staying on track with your treatment with VRAYLAR® (cariprazine), and leading a healthy lifestyle can help you manage your bipolar I condition.

You'll find additional resources and information about bipolar I disorder at VRAYLAR.com.

IMPORTANT RISK INFORMATION (continued)

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 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. Talk to your healthcare provider about the risk to your unborn baby if you take VRAYLAR during pregnancy. If you become pregnant or think you are 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

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 were 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.

Please see Important Risk Information throughout and Prescription Drug Facts, including Boxed Warnings, enclosed within this brochure.

A large, empty, lined writing area with a teal border and a light blue background. The area is filled with horizontal lines, providing space for notes. The lines are evenly spaced and extend across the width of the page. The bottom right corner of the writing area is slightly rounded.

VRAYPAYSM may help you save.

The VRAYLAR savings card may help eligible commercially insured patients lower their out-of-pocket costs for VRAYLAR prescriptions.*

It's easy to join



Sign up via text:

Simply activate or receive a savings card by texting VRAYLAR to 75186.†



Sign up online:

Simply activate or receive a savings card by visiting allergansavingscard.com/vraylar

It's easy to save

Most commercially insured eligible patients may save on VRAYLAR prescriptions.* To learn more about this offer, go to allergansavingscard.com/vraylar

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Vraylar[®]
(cariprazine) capsules
1.5mg•3mg•4.5mg•6mg

* Terms, Conditions, and Eligibility apply. For details, see <https://www.allergansavingscard.com/vraylar>

† Messages and data rates apply. Reply HELP for help; reply STOP to cancel.

Message frequency depends on user. Consent not required to purchase goods/services.

SMS Terms: <https://smsterms.copaysavingsprogram.com/vraylar>

Privacy Policy: <https://smsprivacy.copaysavingsprogram.com/vraylar>

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Prescription Drug Facts for VRAYLAR[®]

Uses

- Short-term (acute) treatment of manic or mixed episodes that happen with bipolar I disorder in adults
- Treatment of depressive episodes that happen with bipolar I disorder (bipolar depression) in adults

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

Warnings

Most important information about VRAYLAR:

Increased risk of death in elderly people with dementia-related psychosis. Elderly people with dementia-related psychosis (having lost touch with reality due to confusion and memory loss) taking medicines like VRAYLAR are at an increased risk of death. VRAYLAR is not approved for treating patients with dementia-related psychosis.

Increased risk of suicidal thoughts or actions in children and young adults. 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.

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 or go to the nearest hospital emergency room 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).** VRAYLAR may cause movements that you cannot control in your face, tongue, or other body parts. Tardive dyskinesia may not go away, even if you stop taking VRAYLAR. Tardive dyskinesia 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 the 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. Extremely high blood sugar can lead to coma or death. 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. Your healthcare provider should check your blood sugar before or soon after you start VRAYLAR, and regularly during long-term treatment with VRAYLAR.
 - **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** has been reported with VRAYLAR. You and 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. Your healthcare provider may do blood tests during the first few months of treatment with VRAYLAR.
- **Decreased blood pressure (orthostatic hypotension).** 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.
- **Falls.** VRAYLAR may make you sleepy or dizzy, may cause a decrease in your blood pressure when changing position (orthostatic hypotension), and can slow your thinking and motor skills which may lead to falls that can cause fractures or other injuries.
- **Seizures (convulsions)** 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, 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.

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).

Tell your healthcare provider before use about all of your medical conditions and if you have or have had

- heart problems or stroke
- low or high blood pressure
- diabetes or high blood sugar in you or your family
- high levels of total cholesterol, LDL-cholesterol, or triglycerides; or low levels of HDL-cholesterol
- seizures (convulsions)
- kidney or liver problems
- low white blood cell count

Ask your healthcare provider before use if you take

- any prescription and over-the-counter medicines, vitamins, and herbal supplements. VRAYLAR and other medicines may affect each other causing possible serious side effects. VRAYLAR may affect the way other medicines work, and other medicines may affect how VRAYLAR works. Your healthcare provider can tell you if it is safe to take VRAYLAR with your other medicines. Do not start or stop any medicines while taking VRAYLAR without talking to your healthcare provider first.

The most common side effects of VRAYLAR include

- difficulty moving or slow movements
- tremors
- uncontrolled body movements
- restlessness and feeling like you need to move around
- sleepiness
- nausea
- vomiting
- indigestion

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.

If pregnant or breastfeeding, ask your healthcare provider before use. Tell your healthcare provider if you are pregnant or plan to become pregnant. VRAYLAR may harm your unborn baby. Talk to your healthcare provider about the risk to your unborn baby if you take VRAYLAR during pregnancy. Tell your healthcare provider if you become pregnant or think you are pregnant during treatment with VRAYLAR. 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/>. If breastfeeding or planning to breastfeed, talk to your healthcare provider about the best way to feed your baby during treatment with VRAYLAR. It is not known if VRAYLAR passes into your breast milk.

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: 08/19