

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

IMPORTANT SAFETY 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.

IMPORTANT SAFETY INFORMATION

VRAYLAR and antidepressants may increase suicidal thoughts or actions in some children and young adults especially within the first few months of treatment or when the dose is changed. Depression and other 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 VRAYLAR or the antidepressant is started or when the dose is changed. Report any change in these symptoms immediately to the doctor.

Please see additional Important Safety Information throughout and full Prescribing Information, including Boxed Warnings and Medication Guide.

Every beginning holds possibilities.



Feeling overconfident in

your abilities

You've taken an important step in treating your bipolar I with VRAYLAR. The following pages are here to help you learn more about your treatment, as well as other ways to keep you feeling supported. Remember, you're not alone—2,500,000 Americans will live with bipolar I in their lifetime.*

To get started, it's important to familiarize yourself with some of the possible symptoms of bipolar I and keep track of your mood shifts, so you can discuss them with your healthcare provider.

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

| Check off all of the DEPRESSIVE SYMPTOMS (also referred to as LOWS) that you've experienced for at least 2 weeks . | | | | | |
|--|---------------------------------------|------------|--|--|--|
| 0 | Feeling very down or sad | 0 | Forgetting things a lot | | |
| 0 | Sleeping too much or too little | \bigcirc | Changes in appetite or weight | | |
| 0 | Having trouble sleeping | \bigcirc | Feeling tired or slowed down | | |
| 0 | Feeling like you can't enjoy anything | 0 | Having little to no interest or pleasure in your hobbies | | |
| 0 | Feeling worried and empty | \bigcirc | Thinking about death or suicide | | |
| \bigcirc | Having trouble concentrating | | | | |

IMPORTANT SAFETY 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.

| | eck off all of the MANIC SYMPTC t you've had for at least 1 week . | OMS (| (also referred to as HIGHS) |
|---|--|-------|---|
| 0 | Having higher than usual energy levels | 0 | Becoming agitated, irritable, or touchy |
| 0 | Feeling jumpy or wired | 0 | Feeling like your thoughts are coming very fast |
| 0 | Not feeling tired or needing little sleep | | |
| | | 0 | Thinking you can do a lot |
| 0 | Becoming more active than usual | | of things at once |
| | | | Behaving impulsively |

Talking really fast about a lot

of different things

Tell your healthcare provider if you've experienced MANIC and DEPRESSIVE symptoms at the same time. This may be what is called a mixed episode. VRAYLAR is proven to treat depressive and short-term manic or mixed episodes that happen with bipolar I in adults.

IMPORTANT SAFETY INFORMATION (continued)

VRAYLAR may cause serious side effects, including (continued):

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.

Please see additional Important Safety Information throughout and full <u>Prescribing Information</u>, including Boxed Warnings and <u>Medication Guide</u>.

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Help take control of your symptoms—with VRAYLAR.



Help find symptom control with VRAYLAR

Living with bipolar I often means a daily struggle to manage the highs and lows to help achieve a feeling of control. Together with the right combination of talk therapy, support, and regular check-ins with your healthcare provider, VRAYLAR can help put symptom control within your reach.



How to take VRAYLAR

Treatments like VRAYLAR start working gradually. Every patient is different. So, it's important to talk to your healthcare provider about how VRAYLAR is working for you. Take your prescribed dose of VRAYLAR by mouth, once a day with or without food. Take VRAYLAR as prescribed by your doctor and do not stop earlier than prescribed, even if you feel better.

IMPORTANT SAFETY INFORMATION (continued)

VRAYLAR may cause serious side effects, including (continued):

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.

Please see additional Important Safety Information throughout and full <u>Prescribing Information</u>, including Boxed Warnings and <u>Medication Guide</u>.



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.

Helps reduce the highs in a manic episode

The highs

Sometimes, when your chemical levels may be too high, VRAYLAR is thought to help decrease the brain receptors' response to these chemicals.

Helps
lift
the lows
in a
depressive
episode

The lows

Sometimes, when your chemical levels may be too low, VRAYLAR is thought to help increase the brain receptors' response to these chemicals.

Will VRAYLAR cause weight gain?

Most people taking VRAYLAR saw no substantial impact on weight.*

In VRAYLAR clinical trials, weight change reported was ≤1.5 lb.

Weight gain may occur. You and your doctor should monitor your weight regularly.

Average weight change in **6- and 8-week** bipolar I depression studies:







Average weight change in **3-week** bipolar mania studies:





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and 8-week bipolar depression trials had no substantial weight gain (defined as ≥ 7% change

^{*}In clinical studies, 99% of patients in 3-week bipolar mania trials and 97% of patients in 6and 8-week bipolar depression trials had no substantial weight gain (defined as ≥ 7% change).

Learn how to save on VRAYLAR with VRAYPAY

Vraylar (cariprazine) capsules
15mg·3mg·45mg·6mg

Join our savings program, **VRAYPAY**SM, and you may be able to decrease your out-of-pocket costs.

Get your savings card and talk to your doctor about a 90-day prescription to save more time and money at the pharmacy.



Go to **VRAYPAY.com** to see how you can save.

Text "VRAYLAR" to 20686 to see if you are eligible to save.*

- * 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

IMPORTANT SAFETY INFORMATION (continued)

VRAYLAR may cause serious side effects, including (continued):

- 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.

More than a savings program

When you sign up for savings, you'll also get access to our patient support program, My Mood Matters. We'll deliver tips, tools, and resources right to your inbox.



Helpful tips & advice

Along with savings, you'll get tips to help you set goals, manage triggers, and stay on track with treatment.



Text reminders & support

You can choose to get medication and refill reminders sent right to your phone. We'll also include tips for living with bipolar I.



Mobile meditation guide

Sign up today and you'll receive an e-book with 10 ways to help you manage your moods through meditation.

IMPORTANT SAFETY INFORMATION (continued)

VRAYLAR may cause serious side effects, including (continued):

- Problems with your metabolism, such as:
 - 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.

Please see additional Important Safety Information throughout and full Prescribing Information, including Boxed Warnings and Medication Guide.

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Simple lifestyle changes that may help you manage your condition.



Stick to the plan

It is important to take your medication as prescribed. Think about your reasons for staying the course, and don't stop taking your medication without first discussing it with your healthcare provider. Discuss any medication changes with your healthcare provider first.



Track your symptoms

Do you know your warning signs? It's a good idea to track any weekly changes and report them to your healthcare provider. You can download a mood tracker at vraylar.com/my-mood-matters



Talk it out

Whether it is a healthcare provider, therapist, family member, or a friend, it's good to have someone to talk to. Who are the people you can call on short notice if you need to?



Make a healthy habit

Eating right, exercising, and getting enough sleep may help to reduce stress. Think of some small changes you could make.



Seek Support

You don't have to do this alone. There are support groups available to help you with everything from housing and legal assistance to health services. Connecting with people who have the same challenges as you can also teach you new ways to cope. Find a local support group and helpful resources at vraylar.com/my-mood-matters



IMPORTANT SAFETY INFORMATION (continued)

VRAYLAR may cause serious side effects, including (continued):

- Problems with your metabolism, such as:
 - 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 additional Important Safety Information throughout and full <u>Prescribing Information</u>, including Boxed Warnings and <u>Medication Guide</u>.



IMPORTANT SAFETY INFORMATION (continued)

VRAYLAR may cause serious side effects, including (continued):

- 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)
- Sleepiness, drowsiness, feeling tired, difficulty thinking and doing normal activities: 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).

IMPORTANT SAFETY 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 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. Taking VRAYLAR during your third trimester of pregnancy may cause your baby to have abnormal muscle movements or withdrawal symptoms after birth. 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.

Please see additional Important Safety Information throughout and full <u>Prescribing Information</u>, including Boxed Warnings and <u>Medication Guide</u>.

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With medication, proper counseling, and a good peer team—there is hope.

*Individual responses to therapy may vary.

VRAYLAR is approved for depressive, acute manic, and mixed episodes of bipolar I disorder in adults.

IMPORTANT SAFETY INFORMATION (continued)

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, indigestion, constipation, feeling tired, trouble sleeping, increased appetite, and dizziness.

These are not all the possible side effects of VRAYLAR.

Please see additional Important Safety Information throughout and full <u>Prescribing</u> Information, including Boxed Warnings and Medication Guide.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

If you are having difficulty paying for your medicine, AbbVie may be able to help. Visit AbbVie.com/myAbbVieAssist to learn more.





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