

### FULL-SPECTRUM RELIEF FOR ALL BIPOLAR I SYMPTOMS

BIPOLAR I DEPRESSION ACUTE MIXED EPISODES

ACUTE MANIA

VRAYLAR is a prescription medicine 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 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.

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.

### You're not alone

About **2.5 million people** in the US will develop bipolar I at some point during their lives.\*

While anyone can develop bipolar I, it often starts in the late teen or early adult years and it lasts a lifetime.

\*Calculations are based on a 1% estimated lifetime prevalence and the estimated population of US residents in November 2024.



"We should support each other and love each other. You've got to make sure your circle is tight and supportive because you need that through this journey."



- Bex, living with bipolar I



"It's important to have hope. I think it's important to be aware of your setbacks, but don't dwell on them. Focus on the things that you're doing well and concentrate on moving forward."

- Gabe, living with bipolar I

Not all of those featured are taking VRAYLAR.

Watch real stories from people living with bipolar I at BPIstories.com

#### **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



### What is bipolar I disorder (bipolar I)?

Bipolar I 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.

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

## What makes bipolar I different from depression?

Bipolar refers to the opposite ends (the poles) of the emotional spectrum—the lows (depression) and the highs (mania).

In addition to the deep, unshakable sadness or emptiness felt by people with major depressive disorder (MDD), people with bipolar I also experience manic episodes.

Treatments for MDD may not be effective for people with bipolar I, so it's important to get the right diagnosis.

## Why is it important to treat all bipolar I mood states?

While depressive symptoms are the most common reason bipolar I patients seek care, manic symptoms are underreported and often undiagnosed. Additionally, 2 in 3 bipolar I depression patients experience at least 1 manic symptom while in a depressive episode. It is important to treat both poles of bipolar I.



### Living with bipolar I

The intense emotional highs and lows of bipolar I can lead to relationship issues, substance abuse, and difficulty at work or school.

Seeking a treatment can be key in managing mood swings. In addition, lifestyle changes, like exercising, getting restful sleep, and eating healthy, are an important part of an effective treatment plan.

# Full-spectrum relief for all bipolar I symptoms

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### Studies have shown VRAYLAR can:



Significantly improve overall bipolar I depressive and manic symptoms\*†



Treat mixed episodes (symptoms of depression and mania at the same time)<sup>+</sup>



Reduce the overall severity of bipolar I. This was observed in three 3-week mania studies\*

\*VRAYLAR was studied in 3-week trials for bipolar I mania and mixed episodes, and in 6- and 8-week trials for bipolar I depression.

<sup>\*</sup>Based on a specific research tool used by healthcare providers.



<sup>5</sup>Approved to treat adults with major depressive disorder (along with an antidepressant), and the full spectrum of bipolar I episodes: depressive, acute manic, or mixed episodes.

Since 2015. Inclusive of all indications

<sup>†</sup>VRAYLAR was not studied to measure symptoms individually.



### How does VRAYLAR work?

While the exact way that VRAYLAR works is unknown, it is thought to work as a partial agonist, meaning it can work in 2 ways: by either turning up OR turning down activity related to certain chemicals in the brain, as needed. This action of helping to manage these chemicals may help control your mood.



### The highs

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

### The lows

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

Visit <u>VRAYLAR.com</u> to learn more about how VRAYLAR works.

### How is VRAYLAR taken?

VRAYLAR is a once-daily pill that can be taken at any time of day with or without food.

Do not stop taking VRAYLAR or change how much you take without checking with your healthcare provider first.

### **IMPORTANT SAFETY INFORMATION (continued)**

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

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.



### 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:



VRAYLAR 5 mg/day



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





\*In clinical studies, 99% of patients in 3-week bipolar mania trials and 97% of patients in 6- and 8-week bipolar depression trials saw no substantial impact on weight (defined as ≥7% change).

"I did my research on it. I learned about medications, therapy, treatments, the differences between highs and lows. And I made an appointment with a specialist."

- Christine, living with bipolar I



## Should I anticipate any sexual side effects when using VRAYLAR?

In bipolar I depression clinical studies, less than 1% of patients taking VRAYLAR reported sexual side effects.

Most common sexual adverse reactions across clinical studies<sup>†</sup>

	Placebo (n=468)	VRAYLAR 1.5 mg/day (n=470)	VRAYLAR 3 mg/day (n=469)
Abnormal orgasm	0%	0%	0.4%
Decreased sex drive	0%	0.2%	0%
Erectile dysfunction	0%	0.6%	0.9%
Delayed ejaculation	0%	0%	0%

<sup>&</sup>lt;sup>†</sup>These adverse events were self-reported by patients.

### 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.
- 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. 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.
  - 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.

## Sharing all your symptoms can help you manage bipolar I



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

If you have experienced any of the following symptoms, be sure to discuss them with your healthcare provider.

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

"Talk to your doctor about it, your primary care physician, your psychiatrist, your counselor. There is no better feeling than to know that I have a team of people helping me."

– Matt, living with bipolar I

HIGHS,	) that	t you've experienced for at least 1 week.
	0	Having higher than usual energy levels
	0	Feeling jumpy or wired
	0	Not feeling tired or needing little sleep
	0	Becoming more active than usual
	0	Talking really fast about a lot of different things
	0	Becoming agitated, irritable, or touchy
	0	Feeling like your thoughts are coming very fast
	0	Thinking you can do a lot of things at once
	0	Behaving impulsively
	0	Feeling overconfident in your abilities
(also r	eferr	all the MIXED-EPISODE SYMPTOMS red to as HIGHS AND LOWS) that you've d at the same time.
	0	Feeling exhausted and overly anxious at the same time
	0	Having too much energy while feeling very sad
	0	Being talkative while pessimistic
	0	Behaving impulsively while feeling exhausted

Check off all the MANIC SYMPTOMS (also referred to as

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 take into consideration the unique characteristics of each patient.

## 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:

- What does it mean if I have a family history of bipolar I?
- 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?
- How might VRAYLAR reduce the severity of my bipolar I?
- How might VRAYLAR improve the symptoms of my bipolar I depression?
- 6 How might VRAYLAR improve the symptoms related to my manic episodes?

#### 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.





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

My current symptor	ns are:
I've tried other ways	s to manage my symptoms; they are
I've made some lifes mood swings; they a	style changes to balance out my are:
Some of my most o	ommon triggers are:

### Breaking through to relief is possible

Talk to your healthcare provider about VRAYLAR.

### **IMPORTANT SAFETY INFORMATION (continued)**

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

 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).



## Tips and tricks that may help manage bipolar I.



#### 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.



### Find peer support groups

Connecting with others who have bipolar I may help you stay on track with treatment and show you new ways to manage your condition. Visit VRAYLAR.com/bipolar to find groups in your area.



### Make healthy a habit

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

Finding a medication that is right for you is also an important part of an effective treatment plan.

Finding the right medication for you could take some time. Treatments like VRAYLAR start working gradually and every patient is different, so it's important to stick with your treatment plan. Do not stop taking VRAYLAR or change how much you take without checking with your healthcare provider first.

### 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



## IMPORTANT SAFETY INFORMATION (continued) What should I tell my healthcare provider before taking VRAYLAR? (continued)

Tell your healthcare provider about any medical conditions and if you (continued):

- 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 <a href="http://www.womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/">http://www.womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/</a>.
- 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.





### You may be able to pay less for VRAYLAR with VRAYPAY™

Eligible commercially insured patients may pay as little as \$0 for VRAYLAR: both 30- and 90-day fills\*

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

Visit VrayPay.com OR
Text VRAYLAR to 20686\* to enroll



of VRAYLAR patients

pay \$10 or less per

Not Actual Card Image

- \*Eligibility: Available to patients with commercial insurance coverage for VRAYLAR\* (cariprazine) who meet eligibility criteria. This co-pay assistance program is not available to patients receiving prescription reimbursement under any federal, state, or government-funded insurance programs (for example, Medicare [including Part D], Medicare Advantage, Medigap, Medicaid, TRICARE, Department of Defense, or Veterans Affairs programs) or where prohibited by law. Offer subject to change or termination without notice. Restrictions, including monthly maximums, may apply. This is not health insurance. For full Terms and Conditions, visit "raypay.com" or call 1-800-761-0436 for additional information. To learn about AbbVie's privacy practices and your privacy choices, visit https://abbv.ie/corpprivacy
- <sup>†</sup>As of November 2024. Out-of-pocket costs may vary by plan design and beneficiary. Please consult your healthcare plan for more specific details related to your coverage.
- \*Text VRAYLAR to 20686 to enroll or activate your savings card and receive refill reminders. Message and data rates may apply. Message frequency varies. You are not required to consent as a condition of receiving goods or services. You can reply HELP for help. You can reply STOP to opt out at any time. By texting VRAYLAR to 20686, you agree to program Terms and Conditions, AbbVie Privacy Policy, and VRAYLAR SMS Terms.

#### INDICATIONS AND USAGE

VRAYLAR is a prescription medicine used 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 (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 Information</u>, including Boxed Warnings, and Medication Guide.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call 1-800-FDA-1088.

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

