

HELP MANAGE THE **HIGHS** OR **LOWS** OF YOUR MOODS WITH **ONE MEDICATION**



If you experience depressive or manic symptoms, ask about VRAYLAR.

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.

Vraylar 
(cariprazine) capsules
1.5mg • 3mg • 4.5mg • 6mg

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 accompanying Prescription Drug Facts including Boxed Warnings.



WHAT EXACTLY IS BIPOLAR I DISORDER?

BIPOLAR I DISORDER

A CONDITION THAT CAUSES PERIODS OF SEVERE CHANGES IN MOOD, ACTIVITY LEVELS, ENERGY, AND THE ABILITY TO CARRY OUT EVERYDAY TASKS. THESE PERIODS ARE KNOWN AS EPISODES.

Bipolar I disorder is thought to be related to how your brain manages dopamine and serotonin, naturally occurring chemicals. When imbalanced, these chemicals can cause unpredictable mood swings between the highs and lows of the condition. If you've been diagnosed with bipolar I disorder, you may have experienced the highs and lows, also known as manic and depressive symptoms.

DID YOU KNOW?

PATIENTS REPORT EXPERIENCING 3 TIMES MORE DEPRESSIVE SYMPTOMS THAN MANIC SYMPTOMS.

While you are probably familiar with the lows, at some point in your life you may have experienced the highs which often go unnoticed. Experiencing these manic symptoms is more common than you realize.

Bipolar I disorder often runs in families. That means if a family member has been diagnosed with bipolar I disorder, you may be more likely to have it.

If you have a family history of bipolar I disorder, be sure to share the symptoms you and your family members have experienced with your healthcare provider.

UNDERSTANDING THE HIGHS AND LOWS OF BIPOLAR I DISORDER

Many people aren't aware of all their bipolar I disorder symptoms. If you've been diagnosed, you may have experienced the highs and lows, also known as manic and depressive symptoms. You may also have experienced both these highs and lows at the same time. This is called a **mixed episode**.

The more you share, the more your healthcare provider can help you find balance.



DEPRESSIVE SYMPTOMS



MANIC SYMPTOMS

EXAMPLES OF:

DEPRESSIVE SYMPTOMS

- Feeling very "down" or sad
- Sleeping too much or too little
- Feeling like you can't enjoy anything
- Feeling worried and empty
- Having trouble concentrating
- Forgetting things a lot
- Eating too much or too little
- Feeling tired or "slowed down"
- Having trouble sleeping
- Thinking about death or suicide

MANIC SYMPTOMS

- Feeling very "up" or "high"
- Feeling "jumpy" or "wired"
- Being agitated, irritable or "touchy"
- Feeling like your thoughts are coming very fast
- Having trouble sleeping
- Becoming more active than usual
- Talking really fast about a lot of different things
- Thinking you can do a lot of things at once
- Doing risky things, like spending a lot of money or having reckless sex

MIXED EPISODES

EXPERIENCING BOTH HIGHS AND LOWS AT THE SAME TIME. EXAMPLES MAY INCLUDE:

- Exhausted but overly anxious
- Having too much energy while feeling very sad
- Being talkative while pessimistic
- Behaving impulsively while feeling exhausted

DID YOU KNOW?

UP TO 40% OF BIPOLAR I DISORDER PATIENTS EXPERIENCE MIXED EPISODES (FEELING MANIC AND DEPRESSIVE SYMPTOMS AT THE SAME TIME)



VRAYLAR HELPS TREAT BIPOLAR DEPRESSION AND MANIA WITH JUST ONE MEDICATION

- VRAYLAR is a once-a-day medication that reduces overall depressive and manic symptoms, even when those symptoms occur at the same time.*
- VRAYLAR reduced the overall severity of one's own condition. This was observed in three 3-week mania studies.†

*VRAYLAR was not studied to measure symptoms individually.

†Based on a specific research tool used by healthcare providers

STARTING AND STAYING ON VRAYLAR

Treatments like VRAYLAR start working gradually. Every patient is different. That's why it's important to talk with your healthcare provider about how VRAYLAR is working for you.

There are some things to keep in mind when taking VRAYLAR.

- Take VRAYLAR once a day, with or without food.
- It's important that you take your prescribed dose of VRAYLAR as directed, even if you start to feel better.
- Do not stop taking VRAYLAR or change how much you take without checking with your healthcare provider first.

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

DEPRESSIVE LOWS OR MANIC HIGHS CAN BE OVERWHELMING

FINDING THE RIGHT BIPOLAR I MEDICATION

There is no known cure for bipolar I disorder, but it is possible to manage your disorder. The first step is to find the right medication—a process that may take time. That's why it's critical to share with your healthcare provider everything you're experiencing as well as any medications you've been prescribed. By evaluating all of your symptoms and treatments, your healthcare provider can help determine the best medication for you.

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**

Please see Important Risk Information throughout and accompanying Prescription Drug Facts including Boxed Warnings.

IMPORTANT RISK INFORMATION (CONTINUED)

VRAYLAR may cause serious side effects, including:

- **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, or blood pressure. These can be symptoms of a rare but potentially fatal side effect called NMS. VRAYLAR should be stopped if you have NMS

TRACKING YOUR SYMPTOMS

HOW MANY HOURS DID YOU SLEEP LAST NIGHT?

DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

RATE YOUR ENERGY LEVEL FOR TODAY

On a scale from 1-5, rate your energy with "1" being much less energy than usual and "5" being much more energy than usual.

DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

DID YOU TAKE MEDICINE TODAY? (Y/N)

DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

HOW TO USE THE MOOD CHART:

At the end of each day, rate your mood by placing a dot in the box that best describes the highest or lowest mood you felt that day. If you have both high and low moods on the same day, place 2 dots.

DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
HIGH MOOD															
ME															
LOW MOOD															

Knowing your symptoms can be very helpful to your healthcare provider. So use this page daily to track your symptoms, then bring it to your next appointment. **For a downloadable, printable PDF of this tracker, go to VRAYLAR.COM**

START DATE: ___/___/___

16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

MEDICINES TAKEN: _____

16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

IMPORTANT RISK INFORMATION (CONTINUED)

VRAYLAR may cause serious side effects, including:

- **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

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IMPORTANT RISK INFORMATION (CONTINUED)

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



HEALTHCARE PROVIDER DISCUSSION GUIDE

Talking with your healthcare provider is an important part of your treatment. But it's not always easy to know where to begin. This set of questions will help you get started. Bring it to your next appointment to discuss whether VRAYLAR may be the right treatment for you.

1. How may VRAYLAR help treat the depressive or manic episodes of my bipolar I disorder?
2. Will VRAYLAR reduce the severity of my overall condition?
3. Will VRAYLAR make me gain weight?
4. What are possible side effects of VRAYLAR?
5. What are some things that can help me manage my depressive and manic episodes?
6. Are there signs that can indicate when I may be having a depressive, manic, or mixed episode?
7. Does my current medication(s) treat depressive, manic, or mixed episodes?

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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
- **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)**

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IMPORTANT RISK INFORMATION (CONTINUED)

VRAYLAR may cause serious side effects, including:

- **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

Please see Important Risk Information throughout and accompanying Prescription Drug Facts including Boxed Warnings.

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
- 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

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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VRAYPAYSM

JOIN OUR PROGRAM FOR SAVINGS ON YOUR VRAYLAR PRESCRIPTIONS

Visit VRAYLAR.com/savings-bipolar to learn more.



**YOU'RE
NEVER
ALONE**

*TREATMENT IS MORE EFFECTIVE THROUGH A
COMBINATION OF MEDICATION AND SUPPORT
GO TO VRAYLAR.COM FOR ADDITIONAL
TOOLS AND RESOURCES*

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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 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. The risk of developing TD and the chance that it will become permanent are thought to increase the longer the 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 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. 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** 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.

When using this product you may have

- 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. 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. 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: 05/2019