

Is your child struggling with acute manic or mixed episodes of bipolar I?

Vraylar 
(cariprazine) capsules

VRAYLAR may help

**break
through**
to relief

The use of VRAYLAR in this pediatric population is based on evidence from well-controlled studies in adults with manic and mixed episodes of bipolar I disorder, studies on how the body affects the medicine in adults and pediatrics, and a pediatric safety study.

INDICATIONS AND USAGE

VRAYLAR is a prescription medicine used to treat short-term (acute) manic or mixed episodes that happen with bipolar I disorder in adults and children ages 10 years and older.

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 increase the risk of suicidal thoughts or actions in people 24 years of age and younger 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.

Understanding bipolar I in children

As a parent or guardian of a child with short-term (acute) manic or mixed episodes of bipolar I, you want to do your best to support them. Taking the time to better understand bipolar I is a great step.

Bipolar I causes periods of significant changes in mood, energy, behavior, and activity levels—often called “mood episodes.”

- While anyone can develop bipolar I, it often starts in the **late teen or early adult years** and lasts a lifetime
- Medical researchers believe that it can result from many factors, including an **imbalance** of certain chemicals in the brain called **neurotransmitters**
- The lifetime prevalence of bipolar disorder among US adolescents has been found to be **higher for females (3.3%) than for males (2.6%)***

*Based on data from the 2001-2004 NIMH National Comorbidity Survey Adolescent Supplement.

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.
- **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.



Did you know?

Bipolar I can often run in families. If there is a history of bipolar I in your family, be sure to let your child's healthcare provider know.

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including [Boxed Warnings](#), and [Medication Guide](#).

Recognizing signs and symptoms of manic and mixed bipolar I episodes in children

During a **MANIC** episode, your child may:

- Feel overly happy, silly, or excitable
- Appear unusually irritable
- Have persistently increased activity or high energy that is noticeable and unusual to people who know them well
- Feel restless or agitated and easily distracted, have racing thoughts, talk quickly, behave impulsively or in risky ways
- Have trouble sleeping but not feel tired

During a **MIXED** episode, your child may:

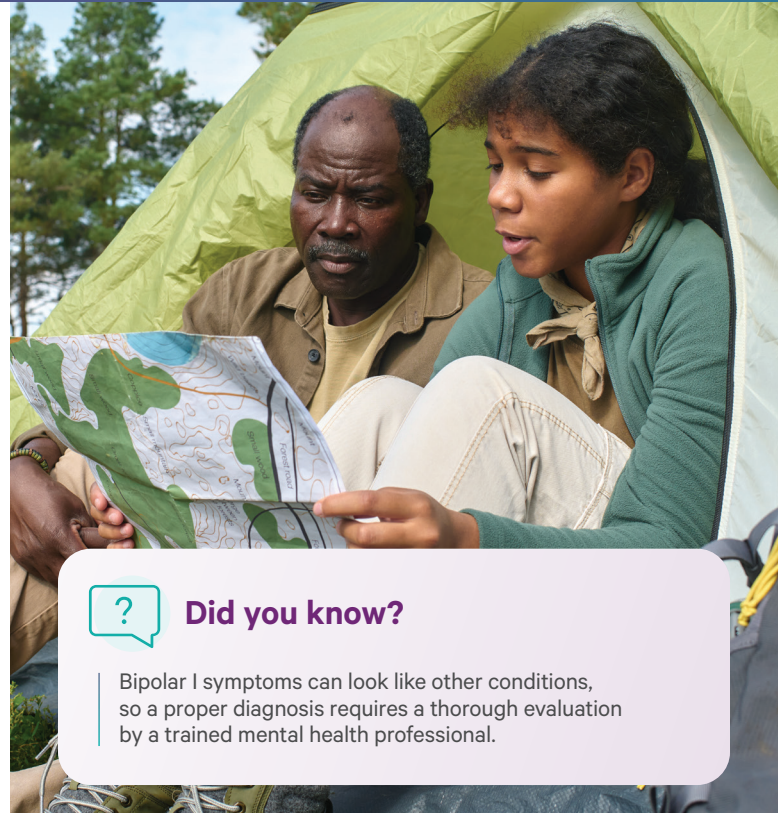
- Feel overly energized while feeling very hopeless
- Feel agitated
- Have extreme changes in appetite
- Have suicidal thoughts
- Have racing thoughts while feeling “slowed down” or experiencing a loss of interest in something once enjoyed

These lists do not include all possible symptoms of manic and mixed episodes. Talk with your child’s healthcare provider about any symptoms you notice.

IMPORTANT SAFETY INFORMATION (continued)

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

- **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.
- **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.



Did you know?

Bipolar I symptoms can look like other conditions, so a proper diagnosis requires a thorough evaluation by a trained mental health professional.

[Click here for additional tools that can help you find a healthcare provider, and resources to help you have informed discussions with them.](#)

IMPORTANT SAFETY INFORMATION (continued)

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

- **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.

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



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Did you know?

In addition to taking medication as prescribed, establishing routines for daily activities, such as sleeping, eating, and exercise, can be an important part of effective treatment.

[Learn more](#) about VRAYLAR.

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

- **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

Why VRAYLAR?

VRAYLAR is approved to treat short-term (acute) manic or mixed episodes that happen with bipolar I disorder in children ages 10 years and older.

About VRAYLAR

VRAYLAR is a once-daily pill that should be taken as directed by your child's healthcare provider. While it can be taken at any time of day, many find it helpful to link taking VRAYLAR to a daily routine, like when your child wakes up or before bed.



One pill



Once a day



Taken any time of day



With or without food

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

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including [Boxed Warnings](#), and [Medication Guide](#).

Questions to ask your child's healthcare provider

If your child has frequent mood swings or has been diagnosed with acute manic or mixed episodes of bipolar I, here are some questions you can ask at their next appointment:

- 1 **What does it mean if there is a history of bipolar I in my family?**
- 2 **How often will my child need follow-up doctor visits?**
- 3 **What treatment goals do you have for my child?**
- 4 **Is there anything we can do at home to help?**
- 5 **How can I be involved in my child's treatment?**

Fill out [this symptom tracker](#) and bring it to your child's next appointment.

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. There is a pregnancy exposure registry for women who are exposed to 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.

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

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

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

800-969-6642

U.S. 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 policy, and supports survivors of suicide loss.

www.afsp.org

888-333-AFSP (2377)

AbbVie does not review or control the content of these websites. This list does not constitute an endorsement by AbbVie.

*AbbVie is a sponsor of this organization.

IMPORTANT SAFETY INFORMATION (continued)

What should I tell my healthcare provider before taking VRAYLAR? (continued):

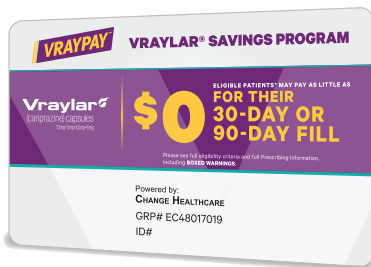
Tell your healthcare provider about all medicines that you take, including prescriptions, over-the-counter medicines, vitamins, and supplements. VRAYLAR may affect the way other medicines work, and other medicines may affect how VRAYLAR works. Do not start or stop any medicines while taking VRAYLAR without talking to your healthcare provider.

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including [Boxed Warnings](#), and [Medication Guide](#).

You may be able to pay less with the VRAYLAR Savings Program

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

Get the Savings Card and talk to your child's healthcare provider about a 90-day prescription to save more time and money at the pharmacy.



Not actual card image.

Visit VRAYLARSavingscard.com OR text **VRAYLAR** to **20686**[†] to enroll

*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 VRAYLARSavingscard.com or call 1-844-4VRAYLAR for additional information. To learn about AbbVie's privacy practices and your privacy choices, visit <https://abbvie.com/privacy>.**

[†]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.

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.

VRAYLAR is available in 0.5 mg, 0.75 mg, 1.5 mg, 3 mg, 4.5 mg, and 6 mg capsules.

Please see the full [Prescribing 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](tel:1-800-FDA-1088).

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

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