IMPORTANCE 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 at the end of 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.

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

*Bipolar disorder includes bipolar I, bipolar II, and other sub-disorders
†National Comorbidity Survey (NCS) 2007. Harvard Medical School

**Living with bipolar I disorder.**

Experiencing the extreme 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 important first step in managing your mood swings. In addition to medication, there are other lifestyle adjustments that can help reduce your symptoms to find more balance.

**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

Please see Important Risk Information throughout and Prescription Drug Facts including Boxed Warnings at the end of this brochure.
FULL-SPECTRUM RELIEF FOR ALL BIPOLAR I SYMPTOMS

Some medications treat only the lows or the highs that happen with bipolar I disorder. VRAYLAR can help smooth both the ups and the downs.* In fact, VRAYLAR:

- Is able to treat manic, depressive and mixed episodes*

*Individual response to therapy may vary.

VRAYLAR was not studied to measure symptoms individually.

HOW VRAYLAR MAY WORK:

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.

DEPRESSED I MAYS EPIDeses | MANIA

FULL-SPECTRUM BIPOLAR I SYMPTOM RELIEF

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.

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 better help your healthcare provider determine if you have bipolar I disorder, review some examples of the symptoms below. You may also want to keep a journal of when your moods move up or down, and share that with your healthcare provider, too.

Check any **DEPRESSIVE SYMPTOMS**, commonly referred to as the **LOWS**, that you’ve experienced for at least **2 weeks**. Examples include:

- 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

Check any **MANIC SYMPTOMS**, commonly referred to as the **HIGHS**, that you’ve experienced for at least **1 week**. Examples include:

- 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
- Being 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 any symptoms of **MIXED EPISODES**, which occur when you experience both **HIGHS** and **LOWS** at the same time. Examples include:

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

**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

Please see Important Risk Information throughout and Prescription Drug Facts including Boxed Warnings at the end of this brochure.
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. Will VRAYLAR reduce the severity of my bipolar I?

5. Will VRAYLAR improve the symptoms of my bipolar depression?

6. Will VRAYLAR improve the symptoms related to my manic episodes?

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 moods, they are:

________________________________________________________________________

________________________________________________________________________

Some of my most common triggers are:

________________________________________________________________________

________________________________________________________________________

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

Please see Important Risk Information throughout and Prescription Drug Facts including Boxed Warnings at the end of this brochure.
InVolVe FrIEnDs AnD FaMIlY

The people closest to you can be helpful when describing your symptoms, so why not bring a friend or family member to your next appointment?

TAkE It OuT

Whether it’s 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 FRIENDS AND FAMILY

The people closest to you can be helpful when describing your symptoms, so why not bring a friend or family member to your next appointment?

STIkC TO THE PlAN

Effective treatment depends on taking your medication as prescribed. Don’t stop taking it just because you are feeling better without first consulting with your healthcare provider.

MAkE HEALtHY A HABIt

Eating right, exercising and getting enough sleep may help 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).

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 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 at the end of this brochure.
YOU’RE ON YOUR WAY

Living with bipolar I disorder brings unique challenges. Everyone is a work in progress. No matter where you are on your journey, remember that it’s a marathon, not a sprint.

Surrounding yourself with people who care, staying on track with your treatment with VRAYLAR® (cariprazine), and leading a healthy lifestyle can help you maintain a feeling of balance.

You’ll find additional resources and information about your condition at VRAYLAR.com.

IMPORTANT RISK INFORMATION (continued)

What should I tell my healthcare provider before taking VRAYLAR?

- 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

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 at the end of this brochure.
VRAYPAY MAY HELP YOU SAVE

The VRAYLAR savings card may help eligible patients lower their out-of-pocket costs of 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:
Eligible patients may save on monthly VRAYLAR prescriptions.
To learn more about this offer, go to:
allergansavingscard.com/vraylar*

Please see Important Risk Information throughout and Prescription Drug Facts including Boxed Warnings at the end of this brochure.

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

HELPs
SmoOth
The Ups
And Downs

*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.

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VRA128635-v2 03/20
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 increased. 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 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. You may experience 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 dizzy.
• Increased body temperature. Do not become too hot or dehydrated during VRAYLAR treatment. Do not exercise too much. Do not exercise 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
• uncontrolled body movements
• tremors
• 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 while taking 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