

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrVRAYLAR[®]

Cariprazine capsules

Read this carefully before you start taking **VRAYLAR** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **VRAYLAR**.

Serious Warnings and Precautions

- VRAYLAR belongs to a group of medicines called atypical antipsychotics. These medicines have been linked to a higher rate of death when used in elderly patients with dementia (loss of memory and other mental abilities).
- VRAYLAR is not to be used if you are elderly and have dementia.

What is VRAYLAR used for?

VRAYLAR is used to treat symptoms of schizophrenia in adults. Not all people with this disorder have the same symptoms. Some of the most common symptoms of schizophrenia may include:

- hallucinations (seeing, feeling, hearing or smelling things that are not there)
- delusions (believing things that are not true)
- paranoia (not trusting others or feeling very suspicious)
- avoiding family members and friends and wanting to be alone
- feeling depressed, anxious or tense

VRAYLAR is also used to manage symptoms in adults who suffer from manic or depressive episodes in bipolar disorder. Bipolar disorder is a condition with symptoms such as:

- bipolar mania (feeling invincible or an all-powerful inflated self-esteem, having racing thoughts, easily losing train of thought, overreacting to what you see or hear, speeding-up your activities, talking very quickly, too loudly, or more than usual, needing less sleep, having poor judgment, severe irritability)
- bipolar depression (feeling sad or hopeless, loss of interest and enjoyment, feeling tired, loss of energy, changes in appetite, sleeping too much, difficulty concentrating)

VRAYLAR is not a cure for your condition, but it can help manage your symptoms and help you feel better.

How does VRAYLAR work?

Antipsychotic medications affect the chemicals that allow communication between nerve cells (neurotransmitters). Illnesses that affect the brain may be due to certain chemicals (dopamine and serotonin) in the brain being out of balance. These imbalances may cause some of the symptoms you may be experiencing. Exactly how VRAYLAR works is unknown. However, it seems to adjust the balance of these chemicals.

What are the ingredients in VRAYLAR?

Medicinal ingredients: cariprazine (as cariprazine hydrochloride)

Non-medicinal ingredients: black iron oxide (1.5 mg, 3 mg and 6 mg only), FD&C Blue 1 (3 mg, 4.5 mg and 6 mg only), FD&C Red 3 (6 mg only), FD&C Red 40 (3 mg and 4.5 mg only), gelatin, magnesium stearate, povidone (4.5 mg only), pregelatinized starch, propylene glycol, shellac, sodium hydroxide (4.5 mg only), titanium dioxide and yellow iron oxide (3 mg and 4.5 mg only).

VRAYLAR comes in the following dosage forms:

Capsules: 1.5 mg, 3 mg, 4.5 mg and 6 mg.

Do not use VRAYLAR if:

- you are allergic to cariprazine or to any of the ingredients in VRAYLAR or its container.
- you are taking:
 - strong or moderate CYP3A4 inhibitors. Strong or moderate CYP3A4 inhibitors should also not be taken for at least 2 weeks after your treatment with VRAYLAR has stopped.
 - Strong or moderate CYP3A4 inducers.Ask your healthcare professional if you are unsure.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VRAYLAR. Talk about any health conditions or problems you may have, including if you:

- are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- exercise vigorously or work in hot or sunny places.
- have low or high blood pressure.
- get dizzy, especially upon standing, or have a history of fainting or feeling sleepy.
- have or are prone to akathisia. It is a movement disorder that includes symptoms such as feelings of restlessness and inability to stay still. VRAYLAR may cause or worsen your symptoms of akathisia.
- have had a stroke or are at risk for stroke.
- have or have a family history of:
 - heart problems
 - any problems with the way your heart beats
 - heart disease
- drink alcohol or use street drugs.
- have a history of alcohol or drug abuse.
- have diabetes or a family history of diabetes as VRAYLAR may increase your blood sugar levels.
- have or have had liver or kidney problems.
- know that you have or have had a low white blood cell count in the past.
- have risk factors for developing blood clots such as:
 - a family history of blood clots
 - being over the age of 65
 - smoking
 - being overweight
 - have a recent major surgery (such as hip or knee replacement)
 - not being able to move due to air travel or other reasons
 - taking oral birth control (“The Pill”)
- have a history of seizures (fits).
- are at risk for aspiration pneumonia.
- are pregnant, think you may be pregnant or plan to become pregnant.
- are breastfeeding or are planning to breastfeed.

Other warnings you should know about:

You may experience side effects several weeks after starting treatment with VRAYLAR, or a dose increase. This is due to the fact that it takes a few weeks for the medicine to accumulate in your body. VRAYLAR can also stay in the body for at least 12 weeks after your treatment has stopped. Your healthcare professional will regularly monitor your overall health while you are taking VRAYLAR. Tell your healthcare professional if you notice any side effects.

VRAYLAR can cause serious side effects, including:

- **Extrapyramidal Symptoms (EPS):** They are a group of symptoms that can occur in people taking antipsychotic medicines such as VRAYLAR. They include:
 - abnormal muscle movements
 - feeling restless
 - inability to stay still (e.g., rocking back and forth while standing or sitting, pacing or marching in place, shifting your weight from foot to foot, crossing and uncrossing your legs while sitting, squirming or fidgeting)
 - shaking
 - muscle stiffness without painEPS may appear early during your treatment with VRAYLAR. Tell your healthcare professional if you experience these symptoms. They may adjust your dose or prescribe you medicines that will help stop these symptoms.
- **Tardive Dyskinesia:** It is a disorder that mainly affects your facial movements and may be irreversible. Your risk of experiencing this serious side effect increases:
 - if you are elderly, especially elderly women;
 - if you take VRAYLAR for a long period of time;
 - the higher the amount of VRAYLAR you take.
- **Suicidal Thoughts or Actions:** If you have thoughts of harming or killing yourself at any time, contact your healthcare professional or go to a hospital **right away**. You may find it helpful to tell a relative or close friend that you are depressed or have other mental illnesses. Ask them to read this leaflet. You might ask them to tell you if they:
 - think your depression or mental illness is getting worse.
 - are worried about changes in your behaviour.
- **Hypotension** (low blood pressure): Some people may faint, or get lightheaded and dizzy while taking VRAYLAR, especially when getting up from a lying or sitting position. This is more likely to happen when you start taking VRAYLAR or as your dose increases. Certain medications, diseases or conditions can make this worse. This will usually pass on its own but if it does not, tell your healthcare professional.
- **Hypertension** (high blood pressure) and **Tachycardia** (abnormally fast heartbeat): You may be at a higher risk of experiencing these serious side effects as your dose of VRAYLAR increases.

See the “**Serious side effects and what to do about them**” table, for more information on these and other serious side effects.

Dehydration and Overheating: VRAYLAR may interfere with your body’s ability to adjust to heat. It is important not to become too hot or dehydrated while you are taking VRAYLAR.

- 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.

Falls: The following symptoms have been reported with the use of antipsychotic medicines, such as VRAYLAR:

- feeling sleepy
- a fall in blood pressure when you stand up from sitting or lying down
- vision problems
- poor balance or lack of coordination

This can lead to falls that may cause fractures or other fall-related injuries. Certain medications, diseases or conditions can make this worse.

Driving and Using Machines: VRAYLAR may affect your judgement, thinking or motor skills, and make you feel sleepy. Give yourself time after taking VRAYLAR to see how you feel before driving a vehicle or using machinery.

Pregnancy and Birth Control:

- Avoid becoming pregnant while you are taking VRAYLAR and for at least 12 weeks after your treatment has stopped. VRAYLAR may harm an unborn baby. Your healthcare professional will discuss the potential risks with you.
- Use a highly effective birth control method while you are taking VRAYLAR and for at least 12 weeks after your treatment. Do not have unprotected sex.
- If you discover that you are pregnant while taking VRAYLAR or within 12 weeks of stopping your treatment, contact your healthcare professional **as soon as possible**. If you are currently taking VRAYLAR, you and your healthcare professional will decide if you should continue to take it while you are pregnant.
- **Pregnancy Registry:** If you become pregnant while taking VRAYLAR, talk to your healthcare professional about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can enroll in this registry by calling 1-866-961-2388. The purpose of this registry is to collect information about the safety of antipsychotic medicines during pregnancy. Information about the registry can also be found at the website:
<http://womensmentalhealth.org/research/pregnancyregistry/atypicalantipsychotic/>.

Effects in Newborns: In some cases, babies born to mothers taking VRAYLAR during pregnancy have symptoms of withdrawal that are severe and require the newborn to be hospitalized. Sometimes, the symptoms may get better on their own. Be ready to seek emergency medical help for your newborn if they:

- have trouble breathing.
- are overly sleepy.
- have muscle stiffness or floppy muscles (like a rag doll).
- are shaking.
- are having trouble feeding.

Breastfeeding:

- It is not known if VRAYLAR can pass into your breast milk and harm a breastfed baby. Therefore, VRAYLAR is not recommended during breastfeeding.
- Talk to your healthcare professional about the best way to feed your baby while you take VRAYLAR.

Check-ups and testing: Your healthcare professional may do check-ups and tests before you start VRAYLAR and during your treatment. These tests may include:

- blood tests to monitor:
 - blood sugar
 - red and white blood cell count
 - amount of platelets
 - lipid levels (a type of fatty substance in your body)
 - that your liver or kidneys are working properly
- blood pressure checks to monitor any changes.
- body weight checks to monitor any weight gain.
- eye examinations to monitor any changes in your vision.

Your healthcare professional may also regularly monitor you for signs of misuse and abuse.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

Do not take VRAYLAR with:

- strong or moderate CYP3A4 inhibitors. Strong or moderate CYP3A4 inhibitors should also not be taken for at least 2 weeks after your treatment with VRAYLAR has stopped.
- strong or moderate CYP3A4 inducers.

Strong and moderate CYP3A4 inhibitors or inducers include but are not limited to:

- medicines used to treat fungal infections (e.g., ketoconazole, itraconazole)
- certain medicines used to treat bacterial infections (e.g., rifampin, erythromycin, clarithromycin)
- medicines used to treat viral infections, including HIV infections and AIDS (e.g., efavirenz)
- medicines used to treat high blood pressure, or chest pain (e.g., bosentan, diltiazem)
- certain medicines used to treat depression
- medicines used to treat seizures (e.g., carbamazepine, phenytoin, phenobarbital)
- certain medicines used to treat inflammation
- St. John's Wort, a herbal remedy
- grapefruit, grapefruit juice, or products containing grapefruit extract

Ask your healthcare professional if you are unsure you are taking them.

The following may also interact with VRAYLAR:

- midazolam, used before surgery to cause sleepiness, relieve anxiety and prevent any memory of the event.
- triazolam, used to treat insomnia.
- digoxin, used to treat various heart conditions.
- dabigatran, used to prevent blood clots.
- cimetidine and ranitidine, used to treat ulcers of the stomach and intestines.
- alcohol. This includes prescription and non-prescription medications that contain alcohol.

Taking VRAYLAR with other medicines may cause possible serious side effects. It can also affect how

VRAYLAR or your other medicines work. Therefore, while you are taking VRAYLAR it is important that you:

- only take medicines prescribed by your healthcare professional.
- talk to your healthcare professional first before starting or stopping any medicines.

How to take VRAYLAR:

- The dose prescribed to you will depend on your medical condition. Your healthcare professional will prescribe you the lowest dose possible needed for your treatment and may increase your dose depending on how you respond to VRAYLAR. Take VRAYLAR exactly as your healthcare professional tells you to take it.
- Even if you feel better, do **NOT** change your dose or stop taking VRAYLAR without talking to your healthcare professional.
- Take VRAYLAR once a day, with or without food.
- Try taking VRAYLAR at the same time each day.

Usual dose:

The usual starting dose is 1.5 mg, once a day.

Schizophrenia

The recommended dose range is 1.5 mg to 6 mg, once a day. The maximum recommended dose is 6 mg per day.

Bipolar mania

The recommended dose range is 1.5 mg to 6 mg, once a day. The maximum recommended dose is 6 mg per day.

Bipolar depression

Your healthcare professional may increase your dose to 3 mg once a day on Day 15 of your treatment. The maximum recommended dose is 3 mg per day.

Overdose:

Symptoms of an overdose with VRAYLAR may include:

- dizziness or light-headedness when standing up
- feeling sleepy

If you think you, or a person you are caring for, have taken too much VRAYLAR, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose by only a few hours, take it as soon as possible. If most of the day has passed since your missed dose, skip that dose and wait until your next scheduled dose. Never take two doses at once.

What are possible side effects from using VRAYLAR?

These are not all the possible side effects you may have when taking VRAYLAR. If you experience any side effects not listed here, tell your healthcare professional.

You may experience side effects several weeks after starting treatment with VRAYLAR, or a dose increase. This is due to the fact that it takes a few weeks for the medicine to accumulate in your body.

Side effects may include:

- back or abdominal pain
- changes in vision
- diarrhea, constipation, indigestion, nausea or vomiting
- excessive sweating
- falls and fractures
- feeling agitated
- feeling tired or sleepy, trouble falling or staying asleep
- headache
- joint pain or stiffness
- painful menstrual periods (women)
- pain in arms, legs, feet or hands
- toothache
- stuffy or runny nose
- frequent urination
- weight gain, changes in appetite (loss or increase)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Extrapyramidal Symptoms (EPS): abnormal muscle movements, including difficulty starting muscle movements, shaking, restlessness or muscle stiffness without pain.		√	
UNCOMMON			
Hyperglycemia (high blood sugar): increased thirst, frequent urination, excessive hunger, headache, blurred vision and fatigue.	√		
Blood clots: swelling, pain and redness in an arm or leg that can be warm to the touch. You may develop sudden chest pain, difficulty breathing and heart palpitations.		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Hypertension (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or heart palpitations.		√	
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up).		√	
Tachycardia (abnormally fast heartbeat)		√	
RARE			
Suicidal Thoughts or Actions: thoughts or attempts to hurt or kill yourself.			√
Neuroleptic Malignant Syndrome: pronounced muscle stiffness or inflexibility with high fever, rapid or irregular heartbeat, sweating, state of confusion, or reduced consciousness.			√
Tardive Dyskinesia: muscle twitching or unusual/abnormal movement of the face or tongue or other parts of your body.		√	
Seizures (fits): loss of consciousness with uncontrollable shaking.			√
Dysphagia: difficulty swallowing that can cause food or liquid to get into your lungs, problems with your esophagus.		√	
Allergic Reaction: difficulty swallowing or breathing, wheezing; drop in blood pressure; feeling sick to your stomach and throwing up; hives or rash; swelling of the face, lips, tongue or throat.			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Hepatitis (inflammation of liver): abdominal pain, fatigue, fever, itchiness, light coloured stool, trouble thinking clearly, yellowing of the skin.			√
Rhabdomyolysis (breakdown of damaged muscle): muscle tenderness, weakness, red-brown (tea-coloured) urine.			√
Stroke (bleeding or blood clot in the brain): sudden numbness, weakness or tingling of the face, arm, or leg, particularly on one side of the body, sudden headache, blurry vision, difficulty swallowing or speaking, or lethargy, dizziness, fainting, vomiting, trouble understanding, trouble with walking and loss of balance.			√
Severe Skin Reactions: fever, severe rash, swollen lymph glands, flu-like feeling, blisters and peeling skin that may start in and around the mouth, nose, eyes and genitals and spread to other areas of the body, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often, less urine.			√
VERY RARE			
Priapism: long-lasting (greater than 4 hours in duration) and painful erection of the penis.			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store between 15 - 30°C. Protect the 3 mg and 4.5 mg capsules from light to prevent the colour of the capsules from fading.
- Keep out of reach and sight of children.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

If you want more information about VRAYLAR:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.abbvie.ca, or by calling 1-888-704-8271.

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