Brightside Specialty Pharmacy

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Patient Education for

VRAYLAR 1.5 MG CAPSULE



Education Section

IMPORTANT:

HOW TO USE THIS INFORMATION: This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

CARIPRAZINE - ORAL (kar-IP-ra-zeen)

COMMON BRAND NAME(S):

Vraylar

WARNING:

There may be a slightly increased risk of serious,

possibly fatal side effects (such as stroke, heart failure, fast/irregular heartbeat, pneumonia) when this medication is used by older adults with dementia. This medication is not approved for the treatment of dementia-related behavior problems. Discuss the risks and benefits of this medication, as well as other effective and possibly safer treatments for dementia-related behavior problems, with the doctor.

Studies have shown that a small number of people (especially people younger than 25) who take antidepressants may have an increased risk of suicidal thoughts or behaviors. Tell the doctor right away if you notice worsening depression/other psychiatric conditions, unusual behavior changes (including possible suicidal thoughts/attempts), or other mental/mood changes (including new/worsening anxiety, panic attacks, trouble sleeping, irritability, hostile/angry feelings, impulsive actions, severe restlessness, very rapid speech). Be especially watchful for these symptoms when a new antidepressant is started or when the dose is changed.

USES:

Cariprazine is used to treat certain mental/mood disorders

(such as bipolar disorder, bipolar depression, schizophrenia).

Cariprazine belongs to a class of drugs known as atypical antipsychotics. It works by helping to restore the balance of certain natural substances in the brain. This medication can decrease hallucinations, help you to think more clearly and positively about yourself, feel less agitated, and take a more active part in everyday life.

Date:8/10/2022

HOW TO USE:

Read the Medication Guide provided by your

pharmacist before you start taking cariprazine and each time you get a refill. If you have any questions, ask your doctor or pharmacist.

Take this medication by mouth with or without food as directed by your doctor, usually once daily.

The dosage is based on your medical condition, response to treatment, and other medications you may be taking. Be sure to tell your doctor and pharmacist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

To reduce your risk of side effects, your doctor may direct you to start this medication at a low dose and gradually increase your dose. Follow your doctor's instructions carefully.

Use this medication regularly to get the most benefit from it. To help you remember, take it at the same time each day.

Do not increase your dose or use this drug more often or for longer than prescribed. Your condition will not improve any faster, and your risk of side effects will increase.

Tell your doctor if your condition does not get better or if it gets worse.

SIDE EFFECTS:

See also Warning section.

Dizziness, lightheadedness, drowsiness, nausea, tiredness, excess saliva/drooling, blurred vision, weight gain, or constipation may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly.

Dizziness and lightheadedness can increase the risk of falling. Get up slowly when rising from a sitting or lying position.

Remember that this medication has been prescribed because your

doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor right away if you have any serious side effects, such as: fainting, trouble swallowing, restlessness (especially in the legs), shaking (tremor), muscle spasm, mask-like expression of the face, seizures, signs of infection (such as sore throat that doesn't go away, fever, chills, cough).

This medication may rarely make your blood sugar rise, which can cause or worsen diabetes. Tell your doctor right away if you have symptoms of high blood sugar such as increased thirst/urination. If you already have diabetes, check your blood sugar regularly as directed and share the results with your doctor. Your doctor may need to adjust your diabetes medication, exercise program, or diet.

This medication may rarely cause a condition called tardive dyskinesia. In some cases, this condition may be permanent. Tell your doctor right away if you develop any unusual uncontrolled movements (especially of the face, mouth, tongue, arms, or legs).

This medication may rarely cause a very serious condition called neuroleptic malignant syndrome (NMS). Get medical help right away if you have any of the following symptoms: fever, muscle stiffness/pain/tenderness/weakness, severe tiredness, severe confusion, sweating, fast/irregular heartbeat, dark urine, signs of kidney problems (such as change in the amount of urine).

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, such as: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS:

See also Warning section.

Before taking cariprazine, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details

Before using this medication, tell your doctor or pharmacist your medical history, especially of: poor blood flow to the brain (such as cerebrovascular disease, stroke), diabetes (including family history), heart problems (such as heart failure, irregular heartbeat), dehydration, high blood pressure, nervous system problems (such as dementia, NMS, seizures), obesity, low white blood cell count (such as history of low white blood cell count caused by medications), swallowing problems.

This drug may make you dizzy or drowsy or blur your vision.

Alcohol or marijuana (cannabis) can make you more dizzy or drowsy. Do not drive, use machinery, or do anything that needs alertness or clear vision until you can do it safely. Limit alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis).

Cariprazine may make you sweat less, making you more likely to get heat stroke. Avoid doing things that may cause you to overheat, such as hard work or exercise in hot weather, or using hot tubs. When the weather is hot, drink a lot of fluids and dress lightly. If you overheat, quickly look for a place to cool down and rest. Get medical help right away if you have a fever that does not go away, mental/mood changes, headache, or dizziness.

Older adults may be more sensitive to the side effects of this drug, especially seizures, drowsiness, dizziness, lightheadedness, confusion, tardive dyskinesia, swallowing problems, and other serious (rarely fatal) side effects. See also Warning section. Drowsiness, dizziness, lightheadedness, and confusion can increase the risk of falling.

Before having surgery, tell your doctor or dentist about all the products you use (such as prescription drugs, nonprescription drugs, and herbal products).

During pregnancy, this medication should be used only when clearly needed. Babies born to mothers who have used this drug during the last 3 months of pregnancy may rarely develop symptoms including muscle stiffness or shakiness, drowsiness, feeding/breathing difficulties, or constant crying. If you notice any of these symptoms in your newborn especially during their first month, tell the doctor right away.

Since untreated mental/mood problems (such as bipolar disorder, schizophrenia) can be a serious condition, do not stop taking this medication unless directed by your doctor. If you are planning pregnancy, become pregnant, or think you may be pregnant, discuss with your doctor right away the benefits and risks of using this medication during pregnancy.

It is unknown if this medication passes into breast milk. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

Drug interactions may change how your

medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (such as prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

A product that may interact with this drug is: metoclopramide. **OVERDOSE**:

If someone has overdosed and has serious symptoms such

as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center.

NOTES:

Do not share this medication with others.

Lab and/or medical tests (such as blood sugar, weight, cholesterol/triglyceride levels) may be done before you start taking this medication and while you are taking it. Keep all medical and lab appointments. Consult your doctor for more details.

MISSED DOSE:

If you miss a dose, take it as soon as you

remember. If it is near the time of the next dose, skip the missed dose. Take your next dose at the regular time. Do not double the dose to catch up.

STORAGE:

Store at room temperature away from light and moisture.

Do not store in the bathroom. Keep all medications away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

Information last revised August 2021.

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