Brightside Specialty Pharmacy

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Patient Education for

QELBREE ER 200 MG CAPSULE

| Education Section |
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| 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.

VILOXAZINE EXTENDED-RELEASE - ORAL (vye-LOX-a-zeen)

COMMON BRAND NAME(S):

Qelbree

WARNING:

A small number of people who take viloxazine for

attention-deficit hyperactivity disorder (ADHD) may experience worsening of their condition, other mental/mood symptoms, or suicidal thoughts/attempts. It is very important to talk with the doctor about the risks and benefits of this medication.

Tell the doctor right away if you notice worsening of your condition/other psychiatric conditions, unusual behavior changes (including possible suicidal thoughts/attempts), or other mental/mood changes (including new/worsening anxiety, panic attacks, depression, trouble sleeping, irritability, hostile/angry feelings, hallucinations, delusions, impulsive actions, severe restlessness, very rapid speech). Be especially watchful for these symptoms when you first start this medication or when the dose is changed.

USES:

Viloxazine is used to treat attention-deficit

hyperactivity disorder (ADHD) as part of a total treatment plan, including psychological, social, and other treatments. It may help to increase the ability to pay attention, concentrate, stay focused, and stop fidgeting. It is thought to work by restoring the balance of certain natural substances (neurotransmitters) in the brain.

HOW TO USE:

Read the Medication Guide provided by your

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

Date:9/27/2022

Take this medication with or without food as directed by your doctor, usually once daily. Swallow the capsules whole. Do not crush, chew, or cut the capsules. Doing so can release all of the drug at once, increasing the risk of side effects.

If you have trouble swallowing the capsules whole, you may open the capsule and sprinkle the contents onto a spoonful of pudding or applesauce. Swallow all of the mixture without chewing. The mixture should be used within 15 minutes if mixing with pudding or within 2 hours if mixing with applesauce. Do not save the mixture for future use.

The dosage is based on your age, medical condition, and response to treatment.

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.

Drowsiness, tiredness, headache, decreased appetite, nausea, vomiting, dry mouth, or constipation may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly.

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.

This medication may raise your blood pressure. Check your blood pressure regularly and tell your doctor if the results are high.

Tell your doctor right away if you have any serious side

effects, including: easy bleeding/bruising, fast heartbeat, unusual weight loss.

Get medical help right away if you have any very serious side effects, including: black stools, vomit that looks like coffee grounds.

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, including: 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:

Before taking viloxazine, 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: bleeding problems, high blood pressure, fast heartbeat, kidney disease, liver disease, personal/family history of mental/mood disorders (such as bipolar disorder, depression, suicidal thoughts).

This drug may make you drowsy or tired. Alcohol or marijuana (cannabis) can make you more drowsy or tired. Do not drive, use machinery, or do anything that needs alertness until you can do it safely. Avoid alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis).

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

During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor.

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

Older adults may be more sensitive to the side effects of this drug, especially bleeding.

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 (including 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.

Some products that may interact with this drug are: other drugs that can cause bleeding/bruising (including antiplatelet

drugs such as clopidogrel, NSAIDs such as ibuprofen/naproxen, "blood thinners" such as dabigatran/warfarin).

Taking MAO inhibitors with this medication may cause a serious (possibly fatal) drug interaction. Avoid taking MAO inhibitors (isocarboxazid, linezolid, metaxalone, methylene blue, moclobemide, phenelzine, procarbazine, rasagiline, safinamide, selegiline, tranylcypromine) during treatment with this medication. Most MAO inhibitors should also not be taken for two weeks before and after treatment with this medication. Ask your doctor when to start or stop taking this medication.

This medication can slow down the removal of other medications from your body, which may affect how they work. Examples of affected drugs include alosetron, duloxetine, ramelteon, tasimelteon, tizanidine, theophylline, among others.

Aspirin can increase the risk of bleeding when used with this medication. However, if your doctor has directed you to take low-dose aspirin for heart attack or stroke prevention (usually 81-162 milligrams a day), you should continue taking it unless your doctor instructs you otherwise. Ask your doctor or pharmacist for more details.

Some products have ingredients that could raise your heart rate or blood pressure. Tell your pharmacist what products you are using, and ask how to use them safely (especially cough-and-cold products, diet aids, or NSAIDs such as ibuprofen/naproxen).

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. Symptoms of overdose may include: severe drowsiness.

NOTES:

Do not share this medication with others.

Lab and/or medical tests (such as pulse, blood pressure, weight) should be done while you are taking this medication. 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.

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