

vortioxetine (Rx)

Brand and Other Names: Trintellix

Classes: Antidepressants, Other

Patient Handout

Patient Education

vortioxetine oral

VORTIOXETINE - ORAL

(VOR-tye-OX-e-teen)

COMMON BRAND NAME(S): Trintellix

WARNING: Antidepressant medications are used to treat a variety of conditions, including depression and other mental/mood disorders. These medications can help prevent suicidal thoughts/attempts and provide other important benefits. However, studies have shown that a small number of people (especially people younger than 25) who take antidepressants for any condition may experience worsening depression, other mental/mood symptoms, or suicidal thoughts/attempts. It is very important to talk with the doctor about the risks and benefits of antidepressant medication (especially for people younger than 25), even if treatment is not for a mental/mood condition. 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: This medication is used to treat depression. Vortioxetine belongs to a class of drugs known as selective serotonin reuptake inhibitors (SSRIs). It works by helping to restore the balance of a certain natural substance (serotonin) in the brain.

HOW TO USE: Read the Medication Guide provided by your pharmacist before you start taking vortioxetine 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. 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. Use this medication regularly to get the most benefit from it. To help you remember, take it at the same time each day. Keep taking this medication even if you feel well. Do not stop taking this medication without consulting your doctor. Some conditions may become worse when this drug is suddenly stopped. Also, you may experience symptoms such as mood swings, headache, muscle stiffness, and runny nose. To prevent these symptoms while you are stopping treatment with this drug, your doctor may reduce your dose gradually. Consult your doctor or pharmacist for more details. Report any new or worsening symptoms right away. It may take up to several weeks before you get the full benefit of this drug. Tell your doctor if your condition does not get better or if it gets worse.

SIDE EFFECTS: See also Warning section. Nausea, constipation, vomiting, and dizziness 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. Tell your doctor right away if you have any serious side effects, including: shaking (tremor), restlessness, inability to keep still, changes in sexual ability, decreased interest in sex, numbness/tingling, easy bleeding/bruising, difficulty concentrating, memory changes, confusion, weakness. Get medical help right away if you have any very serious side effects, including: seizures, black stools, vomit that looks like coffee grounds, eye pain/swelling/redness, widened pupils, vision changes (such as seeing rainbows around lights at night, blurred vision). This medication may increase serotonin and rarely cause a very serious condition called serotonin syndrome/toxicity. The risk increases if you are also taking other drugs that increase serotonin, so tell your doctor or pharmacist of all the drugs you take (see Drug Interactions section). Get medical help right away if you develop some of the following symptoms: fast heartbeat, hallucinations, loss of coordination, severe dizziness, severe nausea/vomiting/diarrhea, twitching muscles, unexplained fever, unusual agitation/restlessness. 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 vortioxetine, 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: personal or family history of bipolar/manic-depressive disorder, personal or family history of suicide attempts, seizures, low sodium in the blood, bleeding problems, personal or family history of glaucoma (angle-closure type). This drug may make you dizzy. Alcohol or marijuana (cannabis) can make you more dizzy. 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). Older adults may be more sensitive to the side effects of this drug, especially bleeding. Older adults may also be more likely to develop a type of salt imbalance (hyponatremia), especially if they are also taking "water pills" (diuretics) with this medication. During pregnancy, this medication should be used only when clearly needed. It may harm an unborn baby. Also, babies born to mothers who have used this drug during the last 3 months of pregnancy may rarely develop withdrawal symptoms such as feeding/breathing difficulties, seizures, muscle stiffness, or constant crying. If you notice any of these symptoms in your newborn, tell the doctor promptly. Since untreated mental/mood problems (such as depression) 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, immediately discuss with your doctor the benefits and risks of using this medication during pregnancy. It is unknown if this drug passes into breast milk. Consult your doctor before breastfeeding.

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). Aspirin can increase the risk of bleeding when used with this medication. However, if your doctor has told you to take low-dose aspirin to prevent heart attack or stroke (usually 81-162 milligrams a day), you should keep taking the aspirin

unless your doctor tells you not to. Ask your doctor or pharmacist for more details. Taking MAO inhibitors with this medication may cause a serious (possibly fatal) drug interaction. Do not take any 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 2 weeks before and 21 days after treatment with this medication. Ask your doctor when to start or stop taking this medication. The risk of serotonin syndrome/toxicity increases if you are also taking other drugs that increase serotonin. Examples include street drugs such as MDMA/"ecstasy," St. John's wort, certain antidepressants (including other SSRIs such as fluoxetine/paroxetine, SNRIs such as duloxetine/venlafaxine), among others. The risk of serotonin syndrome/toxicity may be more likely when you start or increase the dose of these drugs.

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 1-800-222-1222. Canada residents can call 1-844-764-7669.

NOTES: Do not share this medication with others. Keep all regular medical and psychiatric appointments. Medical/psychiatric check-ups should be done periodically to monitor your progress or check for side effects.

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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