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2. Vortioxetine

Vortioxetine 49

Pronunciation: VOR-tye-OX-e-teen

Brand name: Trintellix

Dosage form: tablets (5mg, 10mg, 20 mg) **Drug class:** Miscellaneous antidepressants

Medically reviewed by Melisa Puckey, BPharm. Last updated on Sep 26, 2023.

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What is vortioxetine?

Vortioxetine (Trintellix) is an antidepressant used to treat major depressive disorder (MDD) in adults. Vortioxetine is thought to work by increasing levels of serotonin in the brain, serotonin is a neurotransmitter. Vortioxetine's mechanism of action (MOA) is thought to be related to the inhibition of the reuptake of serotonin (5-HT), it has other activities, including 5-HT3 receptor antagonism and 5-HT1A receptor agonism, but it is unclear whether these have an antidepressant effect.

Vortioxetine is classified as a miscellaneous antidepressant, although some class vortioxetine it as a SSRI (selective serotonin reuptake inhibitor) or a serotonin modulator.

Vortioxetine originally became an FDA-approved medicine on September 30, 2013, under the brand name Brintellix. In May 2016, Takeda Pharmaceuticals U.S.A., Inc. and Lundbeck announced that Brintellix would be marketed in the United States under the new name Trintellix effective June 2016. The change comes after receiving reports of name confusion in the marketplace between Brintellix and the anti-blood-clotting therapy Brilinta (ticagrelor).

Vortioxetine side effects

Also see Warnings below.

Common vortioxetine side effects

The most common side effects of vortioxetine that happen in more than 5% of patients and at least twice the rate of placebo in clinical trials were:

- nausea;
- · constipation; or
- · vomiting.

Serious vortioxetine side effects

Get emergency medical help if you have signs of an allergic reaction: hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Report any new or worsening symptoms to your doctor, such as mood or behavior changes, anxiety, panic attacks, trouble sleeping, or if you feel impulsive, irritable, agitated, hostile, aggressive, restless, hyperactive (mentally or physically), more depressed, or have thoughts about suicide or hurting yourself.

Vortioxetine may cause serious side effects. Call your doctor at once if you have:

- racing thoughts, decreased need for sleep, unusual risk-taking behavior, feelings of extreme happiness or sadness, being more talkative than usual;
- vision changes, eye pain, eye redness or swelling;
- easy bruising, unusual bleeding, coughing up blood; or
- low sodium level (may be more likely to occur in older adults--confusion, memory problems, hallucinations, slurred speech, severe weakness, feeling unsteady.

Serotonin syndrome is a potentially life-threatening problem that can happen when you take vortioxetine, with an increased risk with certain other medicines. Seek medical attention right away if you have symptoms of serotonin syndrome, such as agitation, hallucinations, fever, sweating, shivering, fast heart rate, muscle stiffness, twitching, loss of coordination, nausea, vomiting, or diarrhea.

Vortioxetine can cause side effects of sexual dysfunction.

This is not a complete list of side effects, and others may occur. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Vortioxetine side effects (more detail)

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Warnings

Suicidal Thoughts and Behaviors in Adolescents and Young Adults: Some young people have thoughts about suicide when first taking an antidepressant. Stay alert to changes in your mood or symptoms. Report any new or worsening symptoms to your doctor, such as mood or behavior changes, anxiety, panic attacks, trouble sleeping, or if you feel impulsive, irritable, agitated, hostile, aggressive, restless, hyperactive (mentally or physically), more depressed, or have thoughts about suicide or hurting yourself.

Serotonin Syndrome: Increased risk when this medicine is used with other serotonergic agents, but there is also a risk when taken alone. Do not use vortioxetine if you have used an MAO inhibitor in the past 14 days, such as isocarboxazid, methylene blue injection, phenelzine, tranylcypromine, and others. After you stop taking vortioxetine, you must wait at least 21 days before you start taking an MAO inhibitor.

Increased Bleeding Risk: Vortioxetine can increase the risk of bleeding events, and using aspirin, nonsteroidal antiinflammatory drugs, other antiplatelet drugs, warfarin, or other drugs that affect blood clotting may increase that bleeding risk.

Discontinuation Syndrome: Adverse reactions after discontinuation of serotonergic antidepressants, particularly after a sudden discontinuation of these medicines. Whenever possible, a gradual reduction in dosage rather than abrupt cessation is recommended.

Activation of Mania/Hypomania: There is an increased risk of mania or hypomania in patients who have bipolar disorder, so it is important to screen patients for bipolar disorder, mania, or hypomania before starting treatment with this medicine.

Angle Closure Glaucoma: Angle closure glaucoma has occurred in patients with untreated anatomically narrow angles treated with antidepressants.

Low blood sodium levels (Hyponatremia): Can occur when taking some types of antidepressants and may be a result of the syndrome of inappropriate antidiuretic hormone secretion (SIADH). Elderly patients may be at greater risk of developing hyponatremia with a serotonergic antidepressant. Also, patients taking diuretics or otherwise volume-depleted can be at greater risk.

Sexual Dysfunction: Vortioxetine may cause symptoms of sexual dysfunction in males and females.

Before taking this medicine

You should not use this medicine if you have a hypersensitivity or allergy to vortioxetine.

Do not use this medicine if you have used an MAO inhibitor in the past 14 days. After you stop taking vortioxetine, you must wait at least 21 days before you start taking an MAO inhibitor.

Tell your doctor if you also take stimulant medicine, opioid medicine, herbal products, or medicine for depression, mental illness, Parkinson's disease, migraine headaches, serious infections, or prevention of nausea and vomiting. An interaction with vortioxetine could cause a serious condition called serotonin syndrome.

To make sure this medicine is safe for you, tell your doctor if you have ever had:

• bipolar disorder (manic depression), or a history of drug abuse or suicidal thoughts;

- glaucoma;
- · seizures or epilepsy;
- bleeding problems; or
- low levels of sodium in your blood.

Pregnancy

Tell your healthcare provider if you are pregnant or plan to become pregnant, as vortioxetine may harm your unborn baby. Taking this medicine in the last 3 months of pregnancy may cause problems in the newborn, such as withdrawal symptoms, serious lung problems, or other complications in the baby. However, stopping the medicine may not be safe for you. Do not start or stop vortioxetine without asking your doctor.

There is a pregnancy registry for females who have taken vortioxetine during pregnancy. The purpose of the registry is to collect information about the health of mothers and their babies who have been exposed to vortioxetine. If you become pregnant during treatment with this medicine, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visit online at https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/.

Breastfeeding

Tell your healthcare provider if you are breastfeeding or plan to breastfeed as it is not known if vortioxetine passes into breastmilk. Discuss with your doctor about the best way to feed your baby while using this medicine.

1 Vortioxetine pregnancy and breastfeeding warnings (more detail)

How should I take vortioxetine?

Take vortioxetine exactly as prescribed by your doctor. Follow all directions on your prescription label and read all medication guides. Your prescriber may occasionally change your dose.

Vortioxetine is usually taken one time a day, with or without food.

You may have withdrawal symptoms if you stop using vortioxetine suddenly. Ask your doctor before stopping the medicine.

Vortioxetine patient tips (more detail)

Dosing information

Usual Adult Dose for Major Depressive Disorder:

Initial dose: 10 mg orally once a day

Maintenance dose: 5 to 20 mg orally once a day

Maximum dose: 20 mg/day

Discontinuing treatment: at lower doses vortioxetine can be discontinued abruptly. However, for doses of 15 mg/day or

20 mg/day it is recommended if possible to reduce dose to 10 mg/day for one week prior to full discontinuation.

Comments:

Patients should be screened for bipolar disorder, mania, and hypomania before starting treatment.

Patients who do not tolerate higher doses may be maintained on 5 mg orally once a day.

The maximum recommended dose is 10 mg/day in known CYP2D6 poor metabolizers.

Formulations available

Trintellix tablets: 5 mg, 10 mg and 20 mg.

Detailed Vortioxetine dosage information

What happens if I miss a dose?

Take the medicine as soon as you can, but skip the missed dose if it is almost time for your next dose. Do not take two doses at one time.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What should I avoid while taking vortioxetine?

Avoid driving or hazardous activity until you know how this medicine will affect you. Your reactions could be impaired.

What other drugs will affect vortioxetine?

Tell your doctor about all your current medicines. Many drugs can interact with vortioxetine, especially:

- · any other antidepressant;
- buspirone;
- fentanyl, tramadol, meperidine, methadone, or other opioids
- lithium,
- St. John's wort, tryptophan (sometimes called L-tryptophan);
- a blood thinner (warfarin, Coumadin, Jantoven);
- a diuretic or "water pill";
- migraine headache medicine (triptans);
- Medicine that can affect blood clotting NSAIDs (nonsteroidal anti-inflammatory drugs) aspirin, ibuprofen (Advil, Motrin), naproxen (Aleve), celecoxib, diclofenac, indomethacin, meloxicam, and others; or warfarin
- seizure medicine carbamazepine, phenytoin.

This list is not complete and many other drugs may interact with vortioxetine. This includes prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible drug interactions are listed here.

<u>Vortioxetine drug interactions</u> (more detail)

Does vortioxetine interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.



Ingredients:

Trintellix Brand

Active ingredient: vortioxetine hydrobromide

Inactive ingredients: mannitol, microcrystalline cellulose, hydroxypropyl cellulose, sodium starch glycolate, magnesium stearate and film coating consisting of hypromellose, titanium dioxide, polyethylene glycol 400, iron oxide red (5 mg and 20 mg) and iron oxide yellow (10 mg)

Storage

Store at room temperature between 68°F to 77°F (20°C to 25°C).

Company

Takeda Pharmaceuticals America, Inc. Lexington, MA 02421 Marketed by: Lundbeck, Deerfield, IL 60015.

Popular FAQ

Is Trintellix the same as Brintellix?

More FAQ

- Does Trintellix (vortioxetine) cause weight gain or loss?
- How long does it take for Trintellix (vortioxetine) to start working?
- Is Trintellix (vortioxetine) good for anxiety?
- Shall I take Trintellix (vortioxetine) in the night or morning?
- Can I take Cymbalta (duloxetine) and Trintellix (vortioxetine) together?

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References

1. Food and Drug Administration (FDA) Trintellix Product Label

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- Reviews (1,565)
- · Side effects
- Dosage information
- Patient tips
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Trintellix

Professional resources

· Vortioxetine monograph

Other brands

Trintellix

Related treatment guides

• Major Depressive Disorder

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation

ঝ্য Risk data available

CSA Schedule* N/A Not a controlled drug

Approval History Drug history at FDA

User Reviews & Ratings

6.1 / 10

1,565 Reviews

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Trintellix (vortioxetine) 10 mg (TL 10)





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