

MEDICATION GUIDE

TRINTELLIX (trin'-TELL-ix)

(vortioxetine) Tablets

What is the most important information I should know about TRINTELLIX?

TRINTELLIX and other antidepressant medicines may cause serious side effects.

- 1. Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, or young adults within the first few months of treatment.**
- 2. Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions. Some people may have a particularly high risk of having suicidal thoughts or actions.** These include people who have (or have a family history of) bipolar illness (also called manic-depressive illness) or suicidal thoughts or actions.
- 3. How can I watch for and try to prevent suicidal thoughts and actions?**
 - Pay close attention to any changes, especially sudden changes in mood, behavior, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed.
 - Call your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
 - Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call your healthcare provider right away if you have any of the following symptoms, especially if they are new, worse, or worry you:

- | | | |
|--|--------------------------------|--|
| • attempts to commit suicide | • acting on dangerous impulses | • acting aggressive, being angry or violent |
| • thoughts about suicide or dying | • new or worse depression | • new or worse anxiety |
| • feeling agitated, restless, angry or irritable | • trouble sleeping | • an extreme increase in activity or talking (mania) |
| • other unusual changes in behavior or mood | • panic attacks | • new or worse irritability |

What is TRINTELLIX?

TRINTELLIX is a prescription medicine used to treat a certain type of depression called Major Depressive Disorder (MDD).

It is important to talk with your healthcare provider about the risks of treating depression and also the risk of not treating it. You should discuss all treatment choices with your healthcare provider.

- Talk to your healthcare provider if you do not think that your condition is getting better with TRINTELLIX treatment.

Do not take TRINTELLIX if you:

- are allergic to vortioxetine, or any of the ingredients in TRINTELLIX. See the end of this Medication Guide for a complete list of ingredients in TRINTELLIX.
- take a Monoamine Oxidase Inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid.
- Do not take an MAOI within 21 days of stopping TRINTELLIX.
- Do not start TRINTELLIX if you stopped taking an MAOI in the last 14 days.

Before taking TRINTELLIX, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems
- have or had seizures or convulsions
- have mania or bipolar disorder (manic depression)
- have low salt (sodium) levels in your blood

- have or had bleeding problems
- drink alcohol
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if TRINTELLIX will harm your unborn baby. Taking TRINTELLIX while pregnant in your third trimester may cause your newborn baby to have withdrawal symptoms that causes a certain type of breathing problem called Persistent Pulmonary Hypertension of the Newborn (PPHN).
- are breastfeeding or plan to breastfeed. It is not known if TRINTELLIX passes into breast milk. Talk to your healthcare provider about the best way to feed your baby if you take TRINTELLIX.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. TRINTELLIX and some medicines may interact with each other, may not work as well, or may cause serious side effects when taken together.

Especially tell your healthcare provider if you take:

- medicines used to treat migraine headache (e.g., triptans)
- medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclics, lithium, selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), buspirone, or antipsychotics
- MAOIs (including linezolid, an antibiotic)
- Tramadol or fentanyl
- over-the-counter supplements such as tryptophan or St. John's Wort
- nonsteroidal anti-inflammatory drugs (NSAIDs)
- aspirin
- warfarin (Coumadin, Jantoven)
- diuretics
- rifampin
- carbamazepine
- phenytoin
- quinidine

Ask your healthcare provider if you are not sure if you are taking any of these medicines.

Before you take TRINTELLIX with any of these medicines, talk to your healthcare provider about serotonin syndrome. See **“What are the possible side effects of TRINTELLIX?”**.

How should I take TRINTELLIX?

- Take TRINTELLIX exactly as your healthcare provider tells you to take it.
- Take TRINTELLIX at about the same time each day.
- Your healthcare provider may need to change the dose of TRINTELLIX until it is the right dose for you.
- Do not start or stop taking TRINTELLIX without talking to your healthcare provider first. Suddenly stopping TRINTELLIX when you take higher doses may cause you to have side effects
 - Headache
 - Stiff muscles
 - mood swings
 - sudden outburst of anger
 - dizziness or feeling lightheaded
 - runny nose
- TRINTELLIX may be taken with or without food.

If you take too much TRINTELLIX, call the Poison Control Center at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What are the possible side effects of TRINTELLIX?

TRINTELLIX may cause serious side effects, including:

- See **“What is the most important information I should know about TRINTELLIX?”**.
- **serotonin syndrome.** A potentially life-threatening problem called serotonin syndrome can happen when medicines such as TRINTELLIX are taken with certain other medicines. Symptoms of serotonin syndrome may include:
 - agitation, hallucinations, coma or other changes in mental status

- problems controlling your movements or muscle twitching
- fast heartbeat
- high or low blood pressure
- sweating or fever
- nausea or vomiting
- diarrhea
- muscle stiffness or tightness
- **abnormal bleeding or bruising.** TRINTELLIX may increase your risk of bleeding or bruising, especially if you take the blood thinner warfarin (Coumadin®, Jantoven®), a nonsteroidal anti-inflammatory drug (NSAID), or aspirin.
- **hypomania** (manic episodes). Symptoms of manic episodes include:

○ greatly increased energy	○ racing thoughts	○ unusually grand ideas	○ reckless behavior
○ severe problems sleeping	○ talking more or faster than usual	○ excessive happiness or irritability	
- **visual problems**
 - eye pain
 - changes in vision
 - swelling or redness in or around the eye

Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.

- **low levels of salt (sodium) in your blood.** Symptoms of this may include: headache, difficulty concentrating, memory changes, confusion, weakness and unsteadiness on your feet. Symptoms of severe or sudden cases of low salt levels in your blood may include: hallucinations (seeing or hearing things that are not real), fainting, seizures and coma. If not treated, severe low sodium levels can cause death.

Common side effects in people who take TRINTELLIX include:

- nausea
- constipation
- vomiting

These are not all the possible side effects of TRINTELLIX. **Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.**

How should I store TRINTELLIX?

Store TRINTELLIX at room temperature between 59°F to 86°F (15°C to 30°C).

Keep TRINTELLIX and all medicines out of the reach of children.

General information about the safe and effective use of TRINTELLIX.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TRINTELLIX for a condition for which it was not prescribed. Do not give TRINTELLIX to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about TRINTELLIX that is written for healthcare professionals.

What are the ingredients in TRINTELLIX?

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)

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For more information, go to www.TRINTELLIX.com or call 1-877-TAKEDA-7 (1-877-825-3327).

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