

MEDICATION GUIDE
TRINTELLIX (trin'-TELL-ix)
 (vortioxetine)
 Tablets

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

TRINTELLIX can cause serious side effects, including:

- **Increased risk of suicidal thoughts and actions.** TRINTELLIX and other antidepressant medicines may increase suicidal thoughts and actions in some people 24 years of age and younger, **especially within the first few months of treatment or when the dose is changed. TRINTELLIX is not for use in children.**
 - **Depression or other mental illnesses are the most important causes of suicidal thoughts or actions.**

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 or if you develop suicidal thoughts or actions.
- 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 or get emergency help right away if you have any of the following symptoms, especially if they are new, worse, or worry you:

- | | | |
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| • attempts to commit suicide | • acting on dangerous impulses | • acting aggressive or violent |
| • thoughts about suicide or dying | • new or worse depression | • new or worse anxiety or panic attacks |
| • feeling agitated, restless, angry or irritable | • trouble sleeping | • an increase in activity or talking more than what is normal for you |
| • other unusual changes in behavior or mood | | |

What is TRINTELLIX?

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

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)
- have stopped taking an MAOI in the last 14 days
- are being treated with the antibiotic linezolid or intravenous methylene blue

Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI or one of these medicines, including the antibiotic linezolid or intravenous methylene blue.

Do not start TRINTELLIX if you stopped taking an MAOI in the last 14 days.

Do not start taking an MAOI for at least 21 days after you stop treatment with TRINTELLIX.

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

- have or had seizures or convulsions
- have or had bleeding problems
- have, or have a family history of, bipolar disorder, mania or hypomania
- have high pressure in the eye (glaucoma)
- have low sodium levels in your blood
- are pregnant or plan to become pregnant. TRINTELLIX may harm your unborn baby. Taking TRINTELLIX during your third trimester of pregnancy may cause your baby to have withdrawal symptoms after birth or may cause your baby to

be at increased risk for a serious lung problem at birth. Talk to your healthcare provider about the risks to you and your unborn or newborn baby if you take TRINTELLIX during pregnancy.

- Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with TRINTELLIX.
- There is a pregnancy registry for females who are exposed to TRINTELLIX during pregnancy. The purpose of the registry is to collect information about the health of females exposed to TRINTELLIX and their baby. If you become pregnant during treatment with TRINTELLIX, 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/>.
- are breastfeeding or plan to breastfeed. It is not known if TRINTELLIX passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with 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 other medicines may affect each other causing possible serious side effects. TRINTELLIX may affect the way other medicines work and other medicines may affect the way TRINTELLIX works.

Especially tell your healthcare provider if you take:

- medicines used to treat migraine headache called triptans
- tricyclic antidepressants
- fentanyl
- lithium
- tramadol
- tryptophan
- buspirone
- St. John's Wort
- medicines that can affect blood clotting such as aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), warfarin
- diuretics

Ask your healthcare provider if you are not sure if you are taking any of these medicines. Your healthcare provider can tell you if it is safe to take TRINTELLIX with your other medicines.

Do not start or stop any other medicines during treatment with TRINTELLIX without talking to your healthcare provider first. Stopping TRINTELLIX suddenly may cause you to have serious side effects. See, “**What are the possible side effects of TRINTELLIX?**”

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take TRINTELLIX?

- Take TRINTELLIX exactly as your healthcare provider tells you to take it. Your healthcare provider may need to change the dose of TRINTELLIX until it is the right dose for you.
- Take TRINTELLIX 1 time each day.
- TRINTELLIX may be taken with or without food.
- If you take too much TRINTELLIX, call your 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 you take TRINTELLIX with certain other medicines. See, “**Who should not take TRINTELLIX?**” **Call your healthcare provider or go to the nearest hospital emergency room right away** if you have any of the following signs and symptoms of serotonin syndrome:
 - agitation
 - sweating
 - seeing or hearing things that are not real (hallucinations)
 - flushing
 - confusion
 - high body temperature (hyperthermia)

- coma
- fast heart beat
- changes in blood pressure
- dizziness
- shaking (tremors), stiff muscles, or muscle twitching
- loss of coordination
- seizures
- nausea, vomiting, diarrhea
- **Increased risk of bleeding.** Taking TRINTELLIX with aspirin, non-steroidal anti-inflammatory drugs (NSAIDs), warfarin or blood thinners may add to this risk. Tell your healthcare provider right away about any unusual bleeding or bruising.
- **Manic episodes.** Manic episodes may happen in people with bipolar disorder who take TRINTELLIX. Symptoms may include:
 - greatly increased energy
 - racing thoughts
 - unusually grand ideas
 - talking more or faster than usual
 - severe problems sleeping
 - reckless behavior
 - excessive happiness or irritability
- **Discontinuation syndrome.** Suddenly stopping TRINTELLIX may cause you to have serious side effects. Your healthcare provider may want to decrease your dose slowly. Symptoms may include:
 - nausea
 - sweating
 - changes in your mood
 - irritability and agitation
 - dizziness
 - electric shock feeling (paresthesia)
 - tremor
 - anxiety
 - confusion
 - headache
 - tiredness
 - problems sleeping
 - hypomania
 - ringing in your ears (tinnitus)
 - seizures
- **Eye problems (angle-closure glaucoma).** TRINTELLIX may cause a type of eye problem called angle-closure glaucoma in people with certain other eye conditions. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are. Call your healthcare provider if you have eye pain, changes in your vision, or swelling or redness in or around the eye.
- **Low levels of sodium in your blood (hyponatremia).** Low sodium levels in your blood that may be serious and may cause death, can happen during treatment with TRINTELLIX. Elderly people and people who take certain medicines may be at a greater risk for developing low sodium levels in your blood. Signs and symptoms may include:
 - headache
 - difficulty concentrating
 - memory changes
 - confusion
 - weakness and unsteadiness on your feet which can lead to falls

In more severe or more sudden cases, signs and symptoms include:

 - seeing or hearing things that are not real (hallucinations)
 - fainting
 - seizures
 - coma
 - stopping breathing (respiratory arrest)
- **Sexual problems (dysfunction).** Taking TRINTELLIX may cause sexual problems.

Symptoms in males may include:

 - Delayed ejaculation or inability to have an ejaculation
 - Decreased sex drive
 - Problems getting or keeping an erection

Symptoms in females may include:

 - Decreased sex drive
 - Delayed orgasm or inability to have an orgasm

Talk to your healthcare provider if you develop any changes in your sexual function or if you have any questions or concerns about sexual problems during treatment with TRINTELLIX. There may be treatments your healthcare provider can suggest.

The most common side effects of 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 68°F to 77°F (20°C to 25°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 take 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).

This Medication Guide has been approved by the U.S. Food and Drug Administration

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