What is TRINTELLIX (vortioxetine)?

TRINTELLIX is a prescription medicine used in adults to treat a certain type of depression called Major Depressive Disorder (MDD). TRINTELLIX has not been shown to be safe and effective for use in children.

IMPORTANT SAFETY INFORMATION

Suicidal Thoughts & Actions

TRINTELLIX and other antidepressants increase the risk of suicidal thoughts and actions in 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. Pay close attention to any changes, especially new or sudden changes in mood, behavior, thoughts, or feelings, or if you develop suicidal thoughts or actions. Call your doctor or get emergency help right away to report any of these, or if you have symptoms such as suicidal thoughts or actions, impulsivity, aggressive or violent actions, depression, anxiety or panic attacks, agitation, restlessness, anger, irritability, trouble sleeping, an increase in activity or talking, or other unusual changes in behavior or mood; especially if they are new, worse, or worry you.

Please see additional Important Safety Information below.

Savings Card Eligibility Requirements

This offer cannot be used if you are a beneficiary of, or any part of your prescription is covered by: (1) any federal, state, or government-funded healthcare program (for example, Medicare, Medicaid, TRICARE), including a state pharmaceutical assistance program (the Federal Employees Health Benefits FEHB Program is not a government-funded healthcare program for purposes of this offer), (2) the Medicare Prescription Drug Program (Part D), or if you are currently in the coverage gap, or (3) insurance that is paying the entire cost of the prescription. Patient must be age 18 or older and have a valid prescription for TRINTELLIX (vortioxetine). Cash patients are not eligible for this offer.

Savings Card Terms & Conditions

You must meet the Eligibility Requirements and report your use of this offer to any third party that reimburses or pays for any part of the prescription cost. By using this offer you confirm you are permitted to use copay coupons under the terms of the benefit plan(s) covering your prescriptions. You agree not to submit any part of the prescription cost to a government healthcare program. A valid Prescriber ID# is required on the prescription. Offer is valid for 13 uses per calendar year until offer ends. 30-day, 60-day, and 90-day prescriptions count as 1, 2, and 3 uses, respectively. Patients pay at least $10 and receive up to $100, $200, or $300 off their out-of-pocket cost for a 30-day, 60-day, or 90-day prescription, respectively, with maximum total savings of $1,300 per year. If patient's insurance rejects the claim, patient pays at least $75 and receives up to $450 off their out-of-pocket cost for a 30-day prescription, with maximum total savings of $5,850 per year. Patient pays first $10 or $75, as applicable, plus any

cost in excess of the maximum savings amount per prescription listed above. This offer: does not constitute insurance; is not valid with any other discount or program for TRINTELLIX (vortioxetine); may be rescinded, revoked, or amended at any time without notice; and is void where prohibited by law. No reproductions. Limit one offer per person. Notify your provider and pharmacist of any change in your insurance. For questions about this offer, call 1-866-279-0287.

Savings Card Pharmacy Instructions

By submitting this offer for reimbursement to McKesson, you certify that: (1) you have dispensed TRINTELLIX to an eligible patient in accordance with the Eligibility Requirements of this offer and the accompanying prescription; (2) you have not submitted and will not submit a claim for reimbursement for the portion of the prescription covered by this offer to any payor; (3) your participation in this program is consistent with all applicable laws and any obligations, contractual or otherwise, that you may have as a pharmacy provider.

IMPORTANT SAFETY INFORMATION (continued)

Who should not take TRINTELLIX?

Do not start or take TRINTELLIX if you:

- are allergic to vortioxetine or any of the ingredients in TRINTELLIX
- are taking, or have stopped taking within the last 14 days, a medicine called a Monoamine Oxidase Inhibitor (MAOI), including the antibiotic linezolid or intravenous methylene blue

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

What should I tell my doctor before taking TRINTELLIX?

Before taking TRINTELLIX, tell your doctor:

- about all your medical and other health conditions
- if you are pregnant or plan to become pregnant, since TRINTELLIX may harm your unborn baby. Taking TRINTELLIX during your third trimester may cause your baby to have withdrawal symptoms after birth or to be at increased risk for a serious lung problem at birth. Tell your doctor right away if you become or think you are pregnant while taking TRINTELLIX
- if you are breastfeeding or plan to breastfeed, since it is not known if TRINTELLIX passes into your breast milk

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements, since TRINTELLIX and some medicines may cause serious side effects (or may not work as well) when taken together. **Especially tell your doctor if you take:** medicines for migraine headache called triptans; tricyclic antidepressants; lithium; tramadol, fentanyl, meperidine, methadone, or other opioids; tryptophan; buspirone; St. John's Wort; medicines that can affect blood clotting such as aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), warfarin; diuretics; medicines used to treat mood, anxiety, psychotic, or thought disorders, including selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs); or medicines used to treat seizures or convulsions.

What are the possible side effects of TRINTELLIX?

TRINTELLIX may cause serious side effects, including:

- **Serotonin syndrome:** A potentially life-threatening problem that can happen when you take TRINTELLIX with certain other medicines. Call your doctor or go to the nearest emergency room right away if you have any of the following signs and symptoms of serotonin syndrome: agitation; seeing or hearing things that are not real; confusion; coma; fast heart-beat; changes in blood pressure; dizziness; sweating; flushing; high body temperature; shaking, stiff muscles, or muscle twitching; loss of coordination; seizures; nausea, vomiting, diarrhea.

- **Increased risk of bleeding:** Taking TRINTELLIX with aspirin, NSAIDs, warfarin or blood thinners may add to this risk. Tell your doctor 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 including: nausea; sweating; changes in your mood; irritability and agitation; dizziness; electric shock feeling; tremor; anxiety; confusion; headache; tiredness; problems sleeping; hypomania; ringing in your ears; seizures.

- **Eye problems:** 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 doctor if you have eye pain, changes in your vision, or swelling or redness in or around the eye.

- **Low levels of salt (sodium) in your blood:** 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 their 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; fainting; seizures; coma; stopping breathing.

- **Sexual problems:** Taking TRINTELLIX may cause sexual problems. Symptoms in males may include: delayed ejaculation or inability to have an ejaculation, decreased sex drive, or problems getting or keeping an erection. Symptoms in females may include: decreased sex drive, or delayed orgasm or inability to have an orgasm. Talk to your doctor if you develop any changes in your sexual function or if you have any questions or concerns about sexual problems during treatment with TRINTELLIX.

The most common side effects of TRINTELLIX include:

- Nausea
- Constipation
- vomiting

These are not all the possible side effects of TRINTELLIX. Tell your doctor if you have any side effect that bothers you or does not go away.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For additional Important Safety Information, click here for Medication Guide, and discuss with your doctor.

Upon clicking user is taken to:
https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

Upon clicking user is taken to:
https://content.takeda.com/?contenttype=MEDGUIDE&product=TRI&language=ENG&country=GBL&documentnumber=1





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