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.

Frequently Asked Questions for Patients

Important Updates About TRINTELLIX

This information is designed to help patients understand upcoming changes related to TRINTELLIX, including the expiration of FDA-granted market exclusivity, and what these changes may mean for Takeda patient support programs.

1. What does loss of exclusivity mean?

- Every medication has a period of exclusivity, which means only the brand-name version is available for a certain amount of time
- When that period ends, approved generic versions can become available

2. When will the generic version of TRINTELLIX become available?

- After **December 17, 2026**, generic versions of TRINTELLIX may become available
- Brand-name TRINTELLIX will continue to be available for appropriate adult patients with MDD
- Talk with your doctor about a treatment plan moving forward

3. Can I continue to get brand-name TRINTELLIX after December 17, 2026?

- Yes, brand-name TRINTELLIX will still be available for appropriate adult patients with MDD. Talk to your doctor about a treatment plan that is right for you
- Insurance coverage and prior authorization criteria vary by plan, so patients should consult their individual insurance provider to understand any changes that may apply

4. Will there be any changes to the brand-name TRINTELLIX following loss of exclusivity?

- Brand-name TRINTELLIX will remain the same
- The loss of exclusivity does not change how TRINTELLIX is made, its established efficacy and safety profile, or how it should be taken
- Follow your healthcare provider's guidance when taking TRINTELLIX or considering treatment changes

5. What is happening to the TRINTELLIX Savings Card program?

- The TRINTELLIX Savings Card program ends on **December 31, 2026**
- The last day to register for or use the Savings Card at the pharmacy is **December 31, 2026**
- For more information, visit **us.trintellix.com** or call **1-866-279-0287**

6. What is happening with the Takeda Help At Hand program for TRINTELLIX?

- The Takeda Help At Hand program will accept applications for TRINTELLIX until **March 31, 2027**
- The program will end on **December 31, 2028** for TRINTELLIX
- For more information, visit **helpathandpap.com**

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 on pages 2 and 3, and click here for Medication Guide, and discuss with your doctor.

7. What if I can't afford generic options?

- Work with your prescribing healthcare provider, pharmacist, and insurer to determine the best, affordable course of care and treatment to address your individual needs
- The Takeda Help At Hand program will accept applications for TRINTELLIX until **March 31, 2027**
- The program will end on **December 31, 2028** for TRINTELLIX
- For more information, visit **helpathandpap.com**

IMPORTANT SAFETY INFORMATION (cont'd)

Who should not take TRINTELLIX (vortioxetine)?

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.

Please see additional Important Safety Information on page 3, and click here for Medication Guide, and discuss with your doctor.

IMPORTANT SAFETY INFORMATION (cont'd)

- **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.

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.

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

TRINTELLIX is a trademark of H. Lundbeck A/S registered with the U.S. Patent and Trademark Office and used under license by Takeda Pharmaceuticals America, Inc. TAKEDA and the TAKEDA logo are registered trademarks of Takeda Pharmaceutical Company Limited.

©2026 Takeda Pharmaceuticals U.S.A., Inc. All rights reserved. 1-877-TAKEDA-7 (1-877-825-3327).

US-VOR-1848v1.0 09/26