

Doctor discussion guide

Better communication may help your doctor to find the treatment that's right for you. This discussion guide can help you capture what you're feeling and serve as a resource for an open and honest conversation with your doctor about your treatment needs.

Note: This discussion guide is not a diagnostic tool. Having some of the symptoms listed below does not necessarily mean you have Major Depressive Disorder (MDD). Only a doctor or other healthcare professional can diagnose MDD. Please contact your healthcare provider immediately if you are feeling suicidal, or contact the [Suicide & Crisis Lifeline](#) by calling or texting 988.



How would you describe the way you're currently feeling? You indicated:

<input checked="" type="checkbox"/> I'm struggling I have major complaints that need to be addressed.	<input checked="" type="checkbox"/> I feel okay I have a few concerns, but I'm not sure what to do.
<input checked="" type="checkbox"/> I feel better I don't have any specific concerns, but I am curious about my options.	



Talk about which of the following symptoms you have been feeling. You indicated:

<input checked="" type="checkbox"/> Depressed mood	<input checked="" type="checkbox"/> Little interest or pleasure in doing things
<input checked="" type="checkbox"/> Difficulty thinking, concentrating, or making even minor decisions	<input checked="" type="checkbox"/> Low energy or feeling tired
<input checked="" type="checkbox"/> Feeling bad about yourself—that you are a failure or having a lot of guilt	<input checked="" type="checkbox"/> Slowness or restlessness that is noticeable to others
<input checked="" type="checkbox"/> Appetite change or significant weight change	<input checked="" type="checkbox"/> Sleep disturbances
<input checked="" type="checkbox"/> Thoughts of death or hurting yourself in some way	

Having these or other symptoms? Make note of them in the box above to share with your doctor.



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.
- Call your doctor or get emergency help right away if you have new or sudden changes in mood, behavior, thoughts or feelings, if you develop suicidal thoughts or actions, or if you have or develop symptoms that are new, worse, or worry you.

Please see additional Important Safety Information, including Full Boxed WARNING for Suicidal Thoughts and Actions, on pages 3 & 4, and accompanying Medication Guide on pages 5 & 6, and discuss with your doctor.

Continued →



List medication side effects you're concerned about. You indicated:

<input checked="" type="checkbox"/> Constipation	<input checked="" type="checkbox"/> Nausea
<input checked="" type="checkbox"/> Vomiting	<input checked="" type="checkbox"/> Dry mouth
<input checked="" type="checkbox"/> Inability to sleep	<input checked="" type="checkbox"/> Overtired
<input checked="" type="checkbox"/> Changes in weight	<input checked="" type="checkbox"/> Sexual side effects

Concerned about these or other side effects? Make note of them in the box above to share with your doctor.



IMPORTANT SAFETY INFORMATION (cont'd)

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

Please see additional Important Safety Information, including Boxed WARNING for Suicidal Thoughts and Actions, on pages 3 & 4, and accompanying Medication Guide on pages 5 & 6, and discuss with your doctor.

Continued →

It's important to be open and honest at your next appointment. If you've been diagnosed with MDD, be sure to discuss potential treatment options with your doctor, including TRINTELLIX (vortioxetine).

Why TRINTELLIX?

TRINTELLIX has helped reduce the multiple symptoms of MDD (a certain type of depression), based on an overall score on a standardized depression rating scale in multiple 6-to-8 week studies and two maintenance studies vs. sugar pill. **Individual results may vary.**

In short-term studies, based on a standardized depression rating scale, the therapeutic effect of TRINTELLIX was generally seen starting at week 2, with the full effect generally not seen until week 4 or later.

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.

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.

Please see additional Important Safety Information on page 4 and accompanying Medication Guide on pages 5 & 6, and discuss with your doctor.

Continued →

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of TRINTELLIX? (con't)

- **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.

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, including Boxed WARNING for Suicidal Thoughts and Actions, please see accompanying Medication Guide on pages 5 & 6, 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.

©2023 Takeda Pharmaceuticals U.S.A., Inc. All rights reserved.
1-877-TAKEDA-7 (1-877-825-3327).

US-VOR-1310v1.0 11/23



Continued →

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 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.**

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, or if you develop suicidal thoughts or actions. 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:

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

What is TRINTELLIX?

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.

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
- 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

Ask your healthcare provider or pharmacist if you are not sure if you take an 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.

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

- 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
- 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)
- medicines used to treat seizures or convulsions

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.
- Take TRINTELLIX with or without food.
- If you take too much TRINTELLIX, call your Poison Help Line 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, “**Do not take TRINTELLIX if you**”. **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
 - seeing or hearing things that are not real (hallucinations)
 - confusion
 - coma
 - fast heart-beat
 - changes in blood pressure
 - dizziness
 - sweating
 - flushing
 - high body temperature (hyperthermia)
 - 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	◦ anxiety
◦ sweating	◦ confusion
◦ changes in your mood	◦ headache
◦ irritability and agitation	◦ tiredness
◦ dizziness	◦ problems sleeping
◦ electric shock feeling (paresthesia)	◦ hypomania
◦ tremor	◦ 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
 - problems getting or keeping an erection
 - decreased sex drive

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, and 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 health 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)

Distributed and Marketed by:

Takeda Pharmaceuticals America, Inc. Lexington, MA 02421

Marketed by:

Lundbeck, Deerfield, IL 60015

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.

©2013-2023 Takeda Pharmaceuticals America, Inc.

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.

Revised: 8/2023

SPI-0456