DOCTOR DISCUSSION GUIDE



Answering the questions below may give your doctor some information to help them support you on your treatment journey with PrTrintellix®. Bring it to your next appointment to help guide the conversation.

since starting TRINTELLIX?
 On a scale from 1-10, how would you rate your depressive symptoms over the past month? (1 = a lot of worsening of symptoms; 5 = no change in symptoms; 10 = a lot of improvement in symptoms)
Note: You can use the Symptom Tracker, available on trintellix.ca/patient, to help record how you're feeling.
Are you experiencing any side effects?
Are you taking TRINTELLIX with any other medication(s)? List all.
 Do you have any specific goals you would like to set in the next weeks or months? Note: Learn more about Goal Setting at trintellix.ca/patient.
 Is there anything else you'd like to discuss with your doctor during your appointment?
, <u>Grander and a same of the continuous of the c</u>

Safety Information

What is TRINTELLIX used for?

TRINTELLIX is used for treatment of depression in adults (18 years of age or older). TRINTELLIX is used to relieve the symptoms of depression which may include:

- feeling sad
- restless
- irritable
- change in weight or appetite
- having a hard time concentrating or sleeping
- feeling tired
- headaches
- unexplained aches and pains.

Serious Warnings and Precautions

New or worsened emotional or behavioural problems

Treatment with TRINTELLIX or any type of antidepressant medication is most safe and effective when you and your doctor have good communication about how you are feeling. You may find it helpful to tell a relative or close friend that you are depressed and ask them to tell you if they think you are getting worse or if they are worried about changes in your behaviour.

When you first start taking TRINTELLIX or when your dose is adjusted, you may feel worse instead of better. You may feel new or worsened feelings of agitation, hostility, anxiety, or impulsivity.

- During your treatment with TRINTELLIX, it is important that you and your healthcare professional talk regularly about how you are feeling. They will closely monitor you for signs of new or worsened emotions or behaviours while you are taking TRINTELLIX.
- You may find it helpful to tell a relative or close friend that you are depressed. Ask them to read this leaflet. You might ask them to tell you if they:
- think your depression is getting worse, or
- are worried about changes in your behaviour.
- If your depression worsens or you experience changes in your behaviour, **tell your healthcare professional right away**. Do NOT stop taking your medicine as it takes time for TRINTELLIX to work.

Self-harm or suicide

- Antidepressants such as TRINTELLIX can increase the risk of suicidal thoughts or actions.
- If you have thoughts of harming or killing yourself at any time, **tell your healthcare professional** or **go to a hospital right away**. You will be closely observed by your healthcare professional in this situation.

Other warnings you should know about

Ending treatment

Abruptly ending your treatment of TRINTELLIX may cause you to experience discontinuation symptoms. If your doctor recommends that you stop taking TRINTELLIX, they will gradually lower your dose. This may help manage any symptoms of discontinuation, such as dizziness, headache, runny nose; sweating or feel like you are getting a flu; increase in dreams/nightmares, having difficulty sleeping or feeling tired; feeling angry, irritable, confused or having mood swings; muscles ache, feel tight or stiff.

Risk of breaking bone

Taking TRINTELLIX may increase your risk of breaking a bone if you are elderly or have osteoporosis or have other major risk factors for breaking a bone. You should take extra care to avoid falls, especially if you get dizzy or have low blood pressure.

Serotonin toxicity or Neuroleptic malignant syndrome

TRINTELLIX may cause serotonin toxicity (also known as Serotonin syndrome) or Neuroleptic malignant syndrome, rare but potentially life-threatening conditions. They can cause serious changes in how your brain, muscles and digestive system work. You may develop serotonin toxicity or neuroleptic malignant syndrome if you take TRINTELLIX with certain medications used to treat depression, migraine or other mental health problems such as schizophrenia.

Speak to your doctor immediately about ending your treatment with TRINTELLIX if you develop a combination of symptoms, such as: fever, sweating, shivering, diarrhea, nausea, vomiting; muscle shakes, jerks, twitches or stiffness, changes in reflexes, loss of coordination; fast heartbeat, changes in blood pressure; confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma.

Effects on pregnancy and newborns

TRINTELLIX should not be used during pregnancy unless your doctor decides the benefit outweighs the risk to your unborn baby. If you are already taking TRINTELLIX and have just found out that you are pregnant, **you should talk to your doctor immediately**. If you take TRINTELLIX near the end of your pregnancy, you are at higher risk of heavy bleeding shortly after birth. Some newborn babies experienced problems at birth when pregnant women took drugs similar to TRINTELLIX. You should also talk to your doctor if you are planning to become pregnant. It is very important that you **do NOT stop taking TRINTELLIX without first talking to your doctor**.

Eye problems

TRINTELLIX can cause eye problems such as mydriasis. Mydriasis is a condition where your pupils widen in an unusual way. This can cause a build-up of fluid and pressure in your eyes. Tell your doctor right away if you experience vision changes, eye pain, redness in or around the eye.

Driving and using machines

Wait until you know how you feel after you have taken TRINTELLIX for the first time or when changing your dose. Do not drive or use heavy machines until you know how TRINTELLIX affects you.

Effects on sexual function

Taking medicines like TRINTELLIX may increase your risk of having sexual problems. This may continue after TRINTELLIX has been discontinued, including for months or years afterwards in some cases. Tell your healthcare professional if you experience symptoms such as a decrease in sexual desire, performance or satisfaction. Medicines like TRINTELLIX may affect sperm quality. Fertility in some men may be reduced while taking TRINTELLIX.

Do not use TRINTELLIX if:

- you are allergic to vortioxetine or to any other ingredients in TRINTELLIX.
- you take Monoamine Oxidase Inhibitors (MAOIs).
- Ask your doctor or pharmacist if you are not sure if you take a MAOI
- Examples of MAOIs include phenelzine, tranylcypromine, moclobemide, selegiline, rasagiline, linezolid which is an antibiotic, methylene blue which is a dye used in certain surgeries
- If you stopped taking a MAOI within the last 14 days, only start TRINTELLIX if your doctor tells you to

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TRINTELLIX. Talk about any health conditions or problems you may have, including if you:

- have ever had any allergic reaction to medications, food, etc.;
- have any medical conditions, including a history of seizures, liver disease, kidney disease, heart problems;
- are taking or have taken medications (prescription or over-the-counter) and any natural or herbal products within the last 14 days;
- have or previously have had glaucoma or increased pressure in your eyes;
- have a history or family history of mania or bipolar disorder;
- are pregnant or intend to become pregnant;
- are breast-feeding;
- have a tendency to easily develop bruises or have known bleeding tendencies, or have been told you have low platelets;
- have been told you have a low sodium level in the blood;
- take certain medicines which may affect blood clotting and increase bleeding, such as oral anticoagulants (e.g., warfarin), acetylsalicylic acid (ASA) and other nonsteroidal anti-inflammatory drugs (NSAIDs);
- are elderly, had a recent bone fracture, were told you have osteoporosis (weak or brittle bones) or have risk factors for osteoporosis;
- have a history of drug abuse

TRINTELLIX is not for use in children and adolescents under 18 years of age.

Consult the <u>Patient Medication Information</u> for a complete list of warnings and precautions that have not been discussed in this piece, important information about what TRINTELLIX is used for, dosing instructions and side effects.







