

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrTRINTELLIX®

Vortioxetine tablets

Read this carefully before you start taking Trintellix and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Trintellix.

Serious Warnings and Precautions

New or worsened emotional or behaviour problems:

- 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.

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.

How does Trintellix work?

Trintellix belongs to a group of medicines called antidepressants. It is thought to work by correcting the imbalance of serotonin in your brain. This may help ease emotional and physical symptoms of depression.

What are the ingredients in Trintellix?

Medicinal ingredients: Vortioxetine hydrobromide

Non-medicinal ingredients: Hypromellose, Hydroxypropyl cellulose, iron oxide red (5 mg, 15 mg and 20

mg) and/or iron oxide yellow (10 mg and 15 mg), Macrogol 400, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate (type A), titanium dioxide (E 171).

Trintellix comes in the following dosage forms:

Tablets: 5 mg (pink), 10 mg (yellow), 15 mg (orange), or 20 mg (red).

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.

Other warnings you should know about:

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. You might ask them to tell you if they think you are getting worse or if they are worried about changes in your behavior.

You may feel worse instead of better when you first start taking drugs like Trintellix or when changing your dose. Your doctor should closely monitor you. You may have:

- new or worsened feelings of restlessness, agitation, anger, aggression, nervousness, short temperament. **If this happens, speak to your doctor.**
- thoughts about suicide, hurting yourself or other people. Thoughts and actions about suicide can occur especially if you have had thoughts of hurting yourself in the past. Suicidal thoughts and actions can occur in any age group but may be more likely if you are 18 to 24 years old. **If this happens, seek immediate medical help.** Do NOT stop taking Trintellix on your own.

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.

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 a higher risk of heavy bleeding shortly after birth.

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.**

Some newborn babies experienced problems at birth when pregnant women took drugs similar to Trintellix. This happened especially when the drug was taken in the last three months of pregnancy.

Some newborns had:

- required breathing support, tube feeding and a longer stay in the hospital
- difficulty feeding or breathing, fits (seizures), tense or overly relaxed muscles and were jittery and cried constantly.
- vomited, had low blood sugar and body temperature changes
- sleeping difficulties
- a serious condition called Persistent Pulmonary Hypertension in the Newborn (PPHN). This made the babies breathe faster and appear blue.

These symptoms normally resolve over time. However, if your newborn baby has any of these symptoms, please contact your doctor immediately.

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.

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:

Serotonin toxicity (also known as Serotonin syndrome) or Neuroleptic malignant syndrome: Trintellix may cause Serotonin toxicity 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.

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.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Do not use Trintellix if you are taking Monoamine oxidase inhibitors (MAOIs) or have stopped taking an MAOI in the last 14 days. You will need to wait at least 21 days after you stop taking Trintellix before you can start taking an MAOI. Taking MAOIs can increase your chances of having serious side effects. Examples of MAOIs are:

- phenelzine
- tranylcypromine
- moclobemide
- selegiline
- linezolid
- methylene blue

The following may interact with Trintellix:

- other antidepressants, such as Selective Serotonin Reuptake Inhibitors (SSRIs) or Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs) (e.g. fluoxetine, venlafaxine, paroxetine), certain tricyclics (e.g. amitriptyline, desipramine), drugs used to treat schizophrenia (e.g. olanzapine, risperidone), or bipolar depression (e.g. lithium).
- other drugs that affect serotonin, such as lithium, drugs containing tryptophan, St. John's Wort, triptans used to treat migraines.
- certain opioid medicines used to treat pain, such as fentanyl (used in anaesthesia or to treat chronic pain), tramadol, tapentadol, meperidine, methadone, pentazocine.
- certain medicines which may affect blood clotting and increase bleeding, such as oral anticoagulants (e.g. warfarin, dabigatran), acetylsalicylic acid (ASA) and other non-steroidal anti-inflammatory drugs (e.g. ibuprofen).
- certain medicines that can increase the risk of seizures by lowering the seizure threshold (e.g. medicines to treat depression (tricyclics, SSRIs, SNRIs); medicines to treat mental disorders (belonging to the groups called phenothiazines, thioxanthenes, butyrophenones); mefloquin (a medicine to prevent and treat malaria); bupropion (a medicine to treat depression also used to wean from smoking); tramadol (a strong painkiller).
- certain medicines used to treat cough, such as dextromethorphan.
- certain medicines that are strong inhibitors of CYP3A4. Such as itraconazole (antifungal medicine), clarithromycin (antibacterial medicine) and HIV protease inhibitors.
- bupropion (an antidepressant and smoking cessation aid), as this may increase your blood levels of Trintellix.
- rifampicin (an antibiotic) as this may lower your blood levels of Trintellix.

Trintellix and urine drug tests: Taking Trintellix may cause false results. Trintellix may cause a urine drug test to show positive results for methadone. If this happens, a more specific test can be performed.

Trintellix and alcohol: Combining Trintellix with alcohol is not advisable.

How to take Trintellix:

- Take one tablet with a glass of water, with or without food.
- Take exactly as the doctor tells you to take it.

Usual dose:

18 to 64 years of age: The usual dose is 10 mg once a day. Depending on how you respond, your doctor may:

- Increase your maximum dose to 20 mg once a day
- Decrease your minimum dose to 5 mg once a day

65 years of age and over: The usual starting dose is 5 mg once a day.

Stopping treatment

Continue to take Trintellix for as long as your doctor recommends. Do not suddenly stop taking or change the dose without talking to your doctor first. Suddenly stopping treatment or changing the dose may cause unpleasant side effects.

Overdose:

If you think you have taken too much Trintellix, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms. Take the Trintellix container with you when you go to the doctor or hospital.

Some of the signs of an overdose could be:

- Dizziness and nausea
- Diarrhea and stomach discomfort
- Itching of whole body
- Sleepiness
- Reddening of skin
- Fits (seizures)
- A rare condition called serotonin toxicity

Missed Dose:

If you missed a dose of this medication, you do not need to make up the missed dose. Skip the missed dose and continue with your next scheduled dose. Do not take two doses at the same time.

What are possible side effects from using Trintellix?

These are not all the possible side effects you may feel when taking Trintellix. If you experience any side effects not listed here, contact your healthcare professional.

The most common side effects of Trintellix are:

- Abdominal pain, bloating
- Common cold, Influenza (flu) symptoms
- Nausea, vomiting
- Decreased appetite
- Abnormal dreams and difficulty sleeping
- Dizziness
- Dry Mouth

- Diarrhea, Constipation
- Fatigue, sleepiness
- Sedated (feeling calm)
- Body feels itchy
- Joint and muscle pain
- Increase in sweating
- Cough

Other possible side effects of Trintellix may include:

- Abnormal excessive sweating
- Dry eye
- Grinding teeth
- Headache
- Reddening of skin
- Night sweats
- Weight gain
- Muscle twitching
- Yawning
- Dehydration
- Late menstrual cycle (period) and sensitive breasts
- sexual problems (decreases in sexual desire, performance and satisfaction, may also lead to further decreases, which may continue after the drug is stopped)

Trintellix may also cause serious side effects including those mentioned above in “**Other warnings you should know about**” and the table below.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON Urinary Tract Infection: Pain or burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine		X	
UNCOMMON Low platelets: Bruising or unusual bleeding from the skin or other areas		X	
Chest Pain: Discomfort or pressure beneath the breastbone			X
RARE Low sodium level in blood: Symptoms of tiredness, weakness, confusion combined with achy, stiff, or uncoordinated muscles		X	
Hypotension (Low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue		X	
Seizures: Loss of consciousness with uncontrollable shaking ('fit')			X
Mania: Elevated or irritated mood, decreased need for sleep, racing thoughts		X	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Serotonin toxicity: A combination of most or all of the following; confusion, restlessness, sweating, shaking, shivering, high fever, hallucinations, sudden jerking of the muscles, muscle stiffness, feeling very agitated or irritable, fast heartbeat. The severity can increase, leading to loss of consciousness.			X
Gastrointestinal bleeding: vomiting blood or passing blood in stool			X
UNKNOWN FREQUENCY Allergic reactions (that may be serious): skin rash, hives, swelling, swelling of the face, lips, tongue or throat, trouble breathing or swallowing, and/or a sudden drop in blood pressure (making you feel dizzy or lightheaded)			X
Glaucoma: Increased pressure in your eyes, eye pain, enlarged pupils and blurred vision		X	
Pancreatitis (swelling of pancreas): upper abdominal pain, fever, rapid heart beat, nausea, vomiting, tenderness when touching the abdomen			X
Increase in the hormone prolactin: In women: breast discomfort, leakage of milk from the breasts, missed periods, or other problems with your menstrual cycle. In men: decreased body and facial hair, breast swelling, leakage of milk from the breasts, difficulty in getting or maintaining erections, or other sexual dysfunction		X	
New or Worsened Emotional or Behavioural Problems: feeling detached, restless, agitated, angry, aggressive, nervous, short tempered		X	
Thoughts of death or suicide Thoughts of hurting yourself or other people			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep out of sight and reach of children.

Store at room temperature (15° to 30°C), protected from moisture.

Do not use Trintellix after the expiry date which is stated on the packaging after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

If you want more information about Trintellix:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.lundbeck.ca>, or by calling 1-800-586-2325.

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