

**PART III: CONSUMER INFORMATION**

Pr **TRINTELLIX**®

Vortioxetine (as vortioxetine hydrobromide)  
5, 10, 15, 20 mg tablets

**This leaflet is part III of a three-part "Product Monograph" published when TRINTELLIX was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about TRINTELLIX. Contact your doctor or pharmacist if you have any questions about the drug.**

**ABOUT THIS MEDICATION**

**What the medication is used for:**

TRINTELLIX is used for treatment of depression (feeling sad, restless, irritable, a change in appetite or weight, difficulty concentrating or sleeping, feeling tired, headaches, unexplained aches and pains) in adults.

**What it does:**

TRINTELLIX belongs to a group of medicines called antidepressants. Depression is thought to be caused by an imbalance of certain chemicals that occur naturally in the brain. TRINTELLIX works to correct the imbalance in one of these chemicals (serotonin). This may help ease emotional and physical symptoms of depression.

**When it should not be used:**

**Do not use TRINTELLIX if:**

- you are allergic to vortioxetine or to any other ingredients of this medicine (see **What the nonmedicinal ingredients are**).
- you are already taking medicines known as monoamine oxidase inhibitors (MAOIs) e.g. phenelzine, tranylcypromine, moclobemide, selegiline, rasagiline, linezolid (an antibiotic), or methylene blue, a dye used in certain surgeries or have recently stopped treatment with an MAOI (within the last 14 days).

Ask your doctor if you are uncertain.

**What the medicinal ingredient is:**

Vortioxetine hydrobromide

**What the nonmedicinal ingredients are:**

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

**What dosage forms it comes in:**

TRINTELLIX tablets are available in 5 mg (pink), 10 mg (yellow), 15 mg (orange), or 20 mg (red) strengths.

**WARNINGS AND PRECAUTIONS**

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

**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.**

**New or Worsened Emotional or Behavioural Problems**

Particularly in the first few weeks or when doses are changed, a small number of patients taking drugs of this type may feel worse instead of better, they may experience new or worsened feelings of agitation, hostility, anxiety, or thoughts about suicide, or harm to others. Suicidal thoughts and actions can occur in any age group but may be more likely in patients 18 to 24 years old. Should this happen to you, or to those in your care, **talk to your doctor immediately**. Close observation by a doctor is necessary in this situation. **Do not discontinue your medication on your own.**

You may be more likely to think like this if you have previously had thoughts about harming yourself.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Your treatment should be closely supervised, especially early during treatment or after dose changes.

**Talk to your doctor or pharmacist before taking TRINTELLIX:**

- if you have ever had any allergic reaction to medications, food, etc;
- about all your medical conditions, including a history of seizures, liver disease, kidney disease, heart problems;
- about all medications (prescription or over-the-counter) and any natural or herbal products you are taking or have taken within the last 14 days, especially monoamine oxidase inhibitors, any other antidepressants, triptans used to treat migraines, lithium, tramadol or drugs containing tryptophan, St. John's Wort;
- if you have glaucoma or increased pressure in your eyes;
- if you have a history or family history of mania or bipolar disorder;

- if you are pregnant or intend to become pregnant, or if you are breastfeeding;
- if you have a tendency to easily develop bruises or have known bleeding tendencies, or have been told you have low platelets;
- if you have been told you have a low sodium level in the blood;
- if you are taking anticoagulants and/or medicinal products known to affect platelet function (non-steroidal anti-inflammatory drugs (NSAIDs) or acetylsalicylic acid (ASA));
- If you had a recent bone fracture or were told you have osteoporosis or risk factors for osteoporosis.
- about your habits of alcohol and/or street drug consumption;
- if you drive a vehicle or perform hazardous tasks during your work.

#### **Effects on Pregnancy and Newborns**

TRINTELLIX should not be used during pregnancy unless the benefit outweighs the risk.

**If you are already taking TRINTELLIX and have just found out that you are pregnant, you should talk to your doctor immediately. 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.

Make sure your midwife and/or doctor know you are on TRINTELLIX.

Some marketing reports indicate that some newborns whose mothers took an SSRI (Selective Serotonin Reuptake Inhibitor) or other newer antidepressants such as TRINTELLIX during pregnancy have developed complications at birth requiring prolonged hospitalization, breathing support and tube feeding. Reported symptoms include: trouble with feeding and/or breathing difficulties, bluish skin, fits (or seizures), body temperature changes, vomiting, low blood sugar, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness and sleeping difficulties. In most cases, the newer antidepressant was taken during the third trimester of pregnancy. These symptoms are consistent with either a direct adverse effect of the antidepressant on the baby, or possibly a discontinuation syndrome caused by sudden withdrawal from the drug. These symptoms normally resolve over time. However, if your newborn baby has any of these symptoms, please contact your doctor immediately.

#### **Persistent Pulmonary Hypertension in the newborn (PPHN) and newer antidepressants:**

When taken during pregnancy, particularly in the last 3 months of pregnancy, an antidepressant including TRINTELLIX may increase the risk of a serious condition

in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

#### **Bone fractures**

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.

### **INTERACTIONS WITH THIS MEDICATION**

**Do not use TRINTELLIX if you are taking Monoamine oxidase inhibitors (MAOIs) (e.g., phenelzine, tranylcypromine, moclobemide, selegiline, linezolid, methylene blue) 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.

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, over-the-counter drugs, vitamins, minerals, natural supplements, or alternative medicines especially:

- other antidepressants, such as SSRIs or 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 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 used to treat cough, such as dextromethorphan.
- 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.

**Combining TRINTELLIX with alcohol is not advisable.**

**PROPER USE OF THIS MEDICATION**

**Usual dose:**

It is very important that you take TRINTELLIX exactly as your doctor has instructed.

**Adults**

The usual adult dose is 10 mg once daily, for adults less than 65 years of age. The dose may be increased by your doctor to a maximum of 20 mg per day or lowered to a minimum of 5 mg per day, depending in how you respond and how well you tolerate treatment.

**Patients 65 years of age or older**

The starting dose is 5 mg per day.

Take one tablet with a glass of water, with or without food.

Continue to take TRINTELLIX for as long as your doctor recommends. Do not suddenly stop taking or change the dose of your medicine without talking to your doctor first. Suddenly stopping treatment or changing the dose may cause unpleasant side effects (see SIDE EFFECTS AND WHAT TO DO ABOUT THEM).

**Remember:** This medicine has been prescribed only for you. Do not give it to anybody else, as they may experience undesirable effects, which may be serious.

**Overdose:**

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Some of the signs of an overdose could be dizziness, feeling sick (nausea), diarrhoea, stomach discomfort, itching on the whole body, sleepiness and flushing. Following intake of dosages several times higher than the prescribed dose, fits (seizures) and a rare condition called serotonin syndrome have been reported.

If you have accidentally taken too much TRINTELLIX contact your doctor or the Regional Poison Control Centre immediately, even if you do not feel sick. Take the TRINTELLIX container with you when you go to the doctor or hospital.

**Missed Dose:**

Take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all medicines TRINTELLIX can cause side effects, although not everybody gets them.

For most patients these side effects are likely to be minor and temporary. However, some may be serious. Talk to your doctor if you experience side effects as the dose may need to be adjusted.

**The most commonly reported side effect (may affect more than 1 in 10 people) with TRINTELLIX is feeling sick (nausea).**

Other **common** side effects (occurring in more than 1 in 100 people, but less than 1 in 10 patients) may include: decreased appetite, abnormal dreams, dizziness, dry mouth, diarrhoea, constipation, vomiting, fatigue, common cold, influenza, back pain, joint pain, sleepiness, sedation, increased sweating and itching on the whole body.

**Uncommon** side effects (occurring in more than 1 in 1,000 people, but less than 1 in 100 patients) may include: dry eye, swelling of abdomen, grinding one’s teeth, skin flushing, night sweats, weight increased, increase in blood lipids, twitching of a muscle, cough, derealisation, and drop in blood pressure.

TRINTELLIX does not usually affect people’s normal activities. However, caution is advised during such activities when beginning TRINTELLIX treatment or changing the dose. Do not drive or operate any tools or machines until you know how TRINTELLIX affects you.

**Discontinuation Symptoms**

Contact your doctor before stopping or reducing your dosage of TRINTELLIX. The most common symptoms associated with suddenly stopping treatment were headache, increased dreaming/nightmares, mood swings, muscle tension/stiffness, sudden outbursts of anger, dizziness/vertigo and nose running. These symptoms usually disappear without needing treatment. Tell your doctor immediately if you have these or any other symptoms. Your doctor may adjust the dosage of TRINTELLIX to reduce the symptoms.

If you develop any other unusual side-effects while taking TRINTELLIX, please talk to your doctor.

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
Symptom / effect		Talk with your doctor or pharmacist		Seek immediate emergency medical assistance
		Only if severe	In all cases	
Uncommon	<b>Low platelets:</b> Bruising or unusual bleeding from the skin or other areas		√	
Rare	<b>Low sodium level in blood:</b> Symptoms of tiredness, weakness, confusion combined with achy, stiff, or uncoordinated muscles		√	
Rare	<b>Seizures:</b> Loss of consciousness with uncontrollable shaking ('fit')			√
Rare	<b>Mania:</b> Overactive behaviour and thoughts		√	
Rare	<b>Serotonin syndrome:</b> A combination of most or all of the following: agitation, tremor, confusion, restlessness, sweating, shaking, shivering, hallucinations, sudden jerking of the muscles, fast heartbeat, labile blood pressure, nausea, vomiting, diarrhoea			√

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
Symptom / effect		Talk with your doctor or pharmacist		Seek immediate emergency medical assistance
		Only if severe	In all cases	
Rare	<b>Gastrointestinal bleeding:</b> vomiting blood or passing blood in stool			√
Unknown	<b>Allergic reactions (that may be serious):</b> 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)			√
Rare	<b>Glaucoma:</b> Increased pressure in your eyes, eye pain and blurred vision		√	
See Warnings And Precautions	<b>New or Worsened Emotional or Behavioural Problems</b>		√	
See Warnings And Precautions	<b>Thoughts of death or suicide</b>			√

*This is not a complete list of side effects. For any unexpected effects while taking TRINTELLIX, contact your doctor or pharmacist.*

**HOW TO STORE IT**

Keep this medicine out of the 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.

**REPORTING SUSPECTED SIDE EFFECTS**

**You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:**

**Report online at  
www.healthcanada.gc.ca/medeffect  
Call toll-free at 1-866-234-2345  
Complete a Canada Vigilance Reporting Form**

**and:**

- Fax toll-free to 1-866-678-6789, or
- Mail to: **Canada Vigilance Program  
Health Canada  
Postal Locator 0701E  
Ottawa, Ontario  
K1A 0K9**

**Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.**

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION**

For questions or concerns and to find the full product monograph prepared for healthcare professionals, go to <http://www.lundbeck.ca> or contact the sponsor, Lundbeck Canada Inc. at 1-800-586-2325.

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