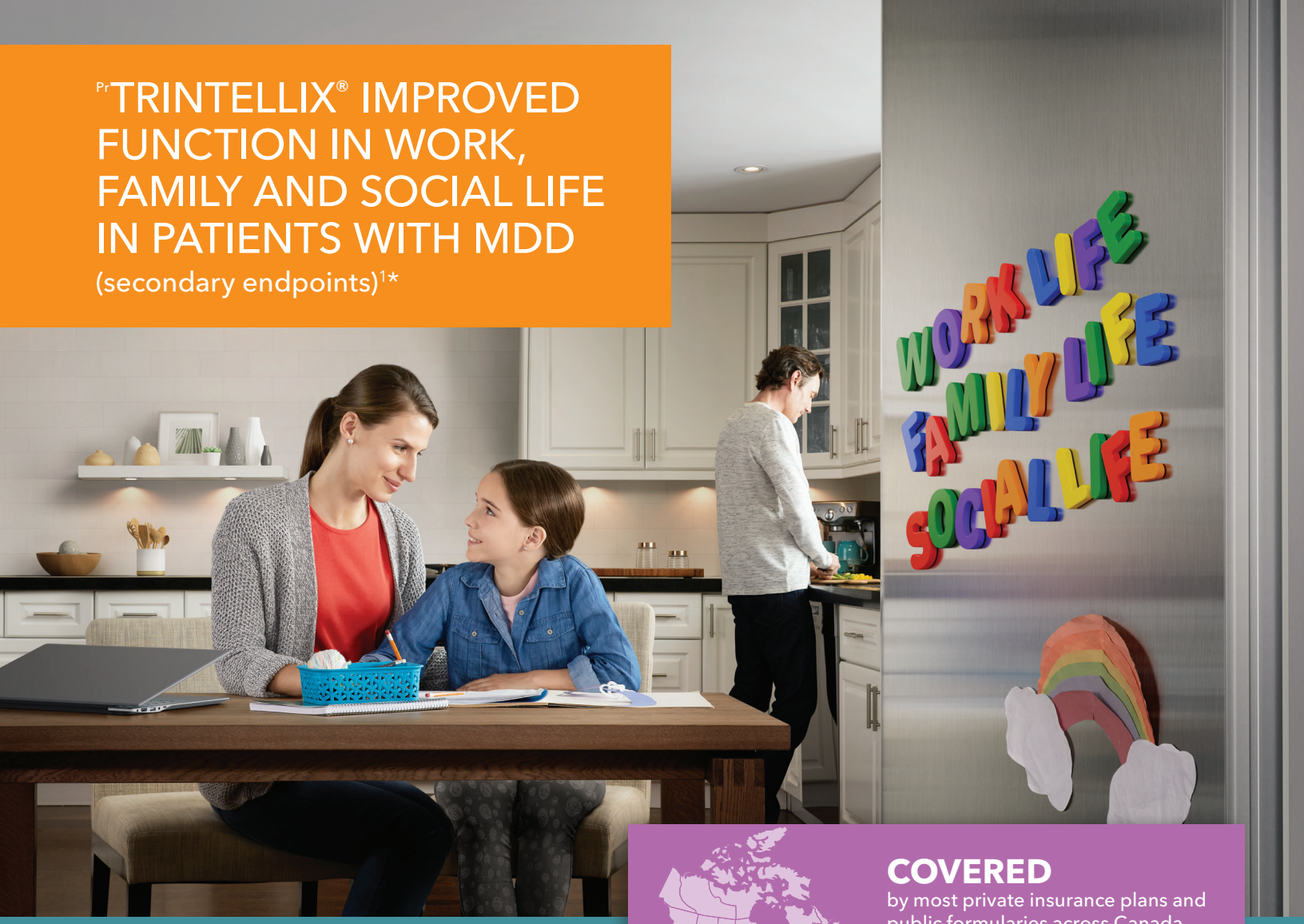
PrTRINTELLIX® IMPROVED FUNCTION IN WORK, FAMILY AND SOCIAL LIFE IN PATIENTS WITH MDD

(secondary endpoints)[1]*



COVERED
by most private insurance plans and public formularies across Canada (restrictions may apply)[2†]

Depressive symptoms (MADRS total score)

Demonstrated 60% improvement from baseline at 8 weeks with Trintellix 20 mg vs 37% with placebo (-18.8 vs -11.7; $p<0.0001$)[1,3*‡]

Anxiety symptoms (HAM-A score)

Demonstrated 51% improvement from baseline at 6 weeks with Trintellix 10 mg vs 37% with placebo (-11.71 vs -8.41; $p<0.001$)[4§]

Overall function (SDS score)

Demonstrated improvement from baseline at 8 weeks with Trintellix 20 mg vs placebo:

Up to 87% improvement in **overall function** (-8.4 vs -4.5; $p=0.0005$)[1*‡]
Up to 86% improvement in function at **work** (-2.6 vs -1.4; $p=0.0059$)[1*‡]
Up to 82% improvement in function at **home** (-3.1 vs -1.7; $p<0.0001$)[1*‡]
Up to 82% improvement in function in a **social setting** (-3.1 vs -1.7; $p<0.0001$)[1*‡]

Visit **Trintellix.ca** for more information

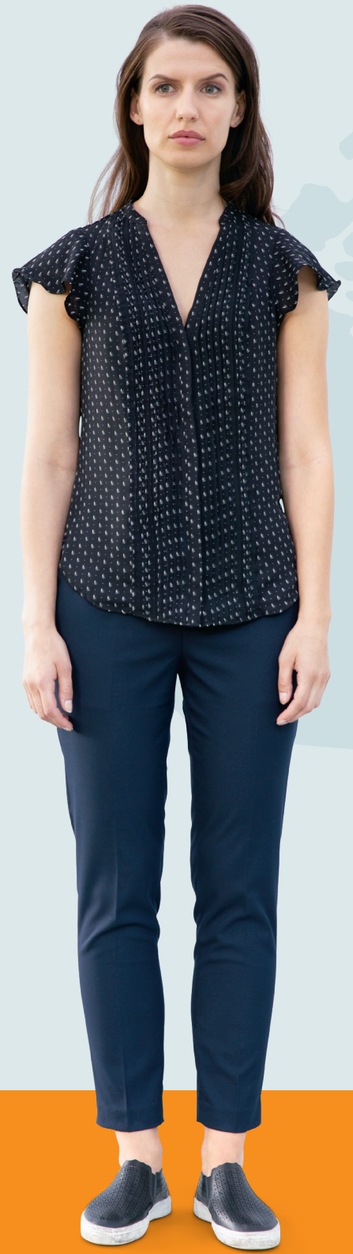
‡ The starting and recommended dose of Trintellix is 10 mg once daily for adults <65 years. See the Product Monograph for complete dosing and administration information.

Trintellix (vortioxetine) is indicated for the treatment of MDD in adults.[3]

HAM-A=Hamilton Anxiety Rating Scale; MADRS=Montgomery-Åsberg Depression Rating Scale; MDD=major depressive disorder; SDS=Sheehan Disability Scale

† Trintellix is eligible for reimbursement by Non-Insured Health Benefits, Veteran Affairs Canada and Correctional Service Canada, and for formulary coverage in the following provinces and territories: Quebec, Ontario, Alberta, Manitoba, Saskatchewan, New Brunswick, Newfoundland and Labrador, Nova Scotia, Prince Edward Island, Northwest Territories, Yukon and British Columbia (special authorization). Refer to provincial formularies for more information.

Pr Trintellix® vortioxetine



MEET SARAH¶

Working Mom, diagnosed with MDD

FACT **Over 3/4** of Canadians who lived with a depressive episode in 2011-2012 were **employed**.[5]

Lifestyle

- Sarah has a busy schedule of meetings and family responsibilities
- Her husband is often away for work, so she takes care of most of the household duties

FACT Depression adversely affects function and work productivity.[5]

Patient's concerns

- In addition to sadness, Sarah's depression makes her feel anxious[6,7]
- She often complains of feeling foggy and finding it hard to concentrate[6,8]
- She feels unmotivated and fatigued, and is overwhelmed by her social life, family and career[6-8]
- Sarah is worried her MDD symptoms are affecting her performance at work[9]

Patient history

- This is her first diagnosis of MDD

Sarah wonders if there is something that can help treat her multiple MDD symptoms.

¶ Fictitious case. May not be representative of the general population.
MDD=major depressive disorder

DEMONSTRATED IMPROVEMENT IN OVERALL FUNCTION (SDS SCORE)

from baseline at 8 weeks with Trintellix 20 mg vs placebo (secondary endpoint):

Up to **87%** improvement in **OVERALL FUNCTION** (-8.4 vs -4.5; p=0.0005)[1*‡]

Up to **86%** improvement in function at **WORK** (-2.6 vs -1.4; p=0.0059)[1*‡]

Up to **82%** improvement in function at **HOME** (-3.1 vs -1.7; p<0.0001)[1*‡]

Up to **82%** improvement in function in a **SOCIAL SETTING** (-3.1 vs -1.7; p<0.0001)[1*‡]

‡ The starting and recommended dose of Trintellix is 10 mg once daily for adults <65 years of age. See the Product Monograph for complete dosing and administration information.

TRINTELLIX WAS SHOWN TO IMPROVE MULTIPLE SYMPTOMS OF MDD

Depressive symptoms
(MADRS total score)

60%
improvement
at 8 weeks
(change from baseline; -18.8 with Trintellix 20 mg vs -11.7 with placebo, $p<0.0001$)

Anxiety symptoms
(HAM-A score)

51%
improvement
at 6 weeks
(change from baseline; -11.41 with Trintellix 10 mg vs -8.41 with placebo, $p<0.001$)

Overall function
(SDS score)

87%
improvement
at 8 weeks
(versus placebo; -8.4 with Trintellix 20 mg vs -4.5 with placebo, $p=0.0005$)

Clinical use:
Efficacy in providing symptomatic relief of MDD demonstrated in trials of up to 8 weeks' duration; efficacy in maintaining an antidepressant response demonstrated for up to 24 weeks.

Physicians who elect to use Trintellix for extended periods should periodically re-evaluate the usefulness of the drug for individual patients.

The lowest effective dose of 5 mg/day should always be used as the starting dose in elderly patients (≥65 years of age).

Not indicated in patients <18 years of age.

Contraindication:
- Combined use with monoamine oxidase inhibitors (MAOIs)

Most serious warnings and precautions:
- **Potential association with behavioural and emotional changes, including self-harm:** Severe agitation-type events reported; rigorous clinical monitoring for suicidal ideation or other indicators of potential for suicidal behaviour is advised in patients of all ages; this includes monitoring for agitation-type emotional and behavioural changes.
- **Discontinuation symptoms:** Gradual reduction in dose, rather than abrupt cessation, is recommended.

Other relevant warnings and precautions:
- Dependence/tolerance
- Caution when driving or operating machinery
- Abnormal bleeding
- Potential for increased risk of postpartum hemorrhage
- Caution in moderate or severe hepatic impairment
- Bone fracture risk
- Caution in patients who have a history of seizures or in patients with unstable epilepsy
- Serotonin syndrome/neuroleptic malignant syndrome
- Cognitive and motor disturbances
- Angle-closure glaucoma
- Caution in patients with a history of mania/hypomania and discontinue use in any patient entering a manic phase
- Aggression/agitation
- Caution with concurrent use of electroconvulsive therapy (ECT)
- Hyponatremia
- Caution in patients with severe renal insufficiency
- Not recommended during breastfeeding
- Dosage adjustment in elderly patients

For more information:
Consult the Product Monograph at www.trintellixmonograph.ca for important information about contraindications, warnings, precautions, adverse reactions, interactions, dosing instructions and conditions of clinical use not discussed in this piece.

The Product Monograph is also available by calling 1-800-586-2325.

DSM=*Diagnostic and Statistical Manual of Mental Disorders*; HAM-A=Hamilton Anxiety Rating Scale; MADRS=Montgomery-Åsberg Depression Rating Scale; MDD=major depressive disorder; MDE=major depressive episode; SDS=Sheehan Disability Scale

* Double-blind, fixed-dose, placebo-controlled study of 608 patients aged 18-75 years with a primary diagnosis of recurrent MDD according to DSM-IV-TR criteria, a current MDE >3 months' duration and a MADRS total score ≥26. Patients were randomized to Trintellix 15 mg, 20 mg (10 mg/day during Week 1 and 15 or 20 mg/day from Weeks 2 to 8) or placebo for 8 weeks. Mean baseline MADRS total scores were 31.5 for placebo, 31.8 for Trintellix 15 mg and 31.2 for Trintellix 20 mg. Mean baseline SDS total scores were 19.8 for placebo, 20.6 for Trintellix 15 mg and 20.7 for Trintellix 20 mg. Mean baseline SDS work scores were 6.3 for placebo, 6.8 for Trintellix 15 mg and 6.9 for Trintellix 20 mg. Mean baseline SDS social scores were 6.8 for placebo, 6.9 for Trintellix 15 mg and 6.8 for Trintellix 20 mg. Mean baseline SDS family scores were 6.9 for placebo, 6.7 for Trintellix 15 mg and 7.0 for Trintellix 20 mg.[1,2]

§ Double-blind, fixed-dose, placebo-controlled, active reference study of 429 patients aged 18-65 with MDD presenting with a current MDE according to DSM-IV-TR criteria and a MADRS total score ≥30 at baseline. Patients were randomized to Trintellix 5 or 10 mg for 6 weeks or placebo. Mean baseline HAM-A total scores were 22.9 for placebo, 21.7 for Trintellix 5 mg and 22.3 for Trintellix 10 mg.

References: 1. Boulenger JP, *et al.* Efficacy and safety of vortioxetine (Lu AA21004), 15 and 20 mg/day: a randomized, double-blind, placebo-controlled, duloxetine-referenced study in the acute treatment of adult patients with major depressive disorder. *Int Clin Psychopharmacol* 2014;29(3):138-49. **2.** Data on file: Trintellix Coverage Canada. Lundbeck. December 2021. **3.** Trintellix Product Monograph. Lundbeck Canada Inc., August 4, 2021. **4.** Alvarez E, *et al.* A double-blind, randomized, placebo-controlled, active reference study of Lu AA21004 in patients with major depressive disorder. *Int J Neuropsychopharmacol* 2012;15(5):589-600. **5.** The Conference Board of Canada. *Healthy brains at work. Estimating the impact of workplace mental health benefits and programs*. Briefing September 2016. www.e-library.ca. Accessed November 23, 2018. **6.** Lam RW, *et al.* Canadian Network for Mood and Anxiety Treatments (CANMAT) 2016 clinical guidelines for the management of adults with major depressive disorder: Section 1. Disease burden and principles of care. *Can J Psychiatry* 2016;61(9):510-23. **7.** Mayo Clinic. Depression (major depressive disorder). https://www.mayoclinic.org/diseases-conditions/depression/symptoms-causes/syc-20356007. Accessed August 15, 2018. **8.** Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. Arlington, VA, American Psychiatric Association, 2013. **9.** Mood Disorders Society of Canada. Health and Wellness in the Workplace. https://mdsc.ca/workplace/health-and-wellness-in-the-workplace/. Accessed December 6, 2018.

Pr Trintellix® vortioxetine

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