

## PART III: CONSUMER INFORMATION

**Pr** PRO-MIRTAZAPINE  
Mirtazapine Tablets, USP

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

**ABOUT THIS MEDICATION****What the medication is used for:**

PRO-MIRTAZAPINE belongs to a group of medicines known as anti-depressants

PRO-MIRTAZAPINE has been prescribed to you to relieve your symptoms of depression. **Treatment with these types of medications is most safe and effective when you and your doctor have good communication about how you are feeling.**

**What it does:**

The way PRO-MIRTAZAPINE works to treat depression is unknown. PRO-MIRTAZAPINE is thought to have an effect in the brain on chemicals called serotonin and norepinephrine.

**When it should not be used:**

Do not use PRO-MIRTAZAPINE if you are:

- allergic to it or any of the components (see section What the non-medicinal ingredients are);
- currently taking or have recently taken monoamine oxidase (MAO) inhibitors (including some types of anti-depressants and anti-Parkinson treatments) (see section INTERACTIONS WITH THIS MEDICATION).

**What the medicinal ingredient is:**

Mirtazapine

**What the non-medicinal ingredients are:**

Colloidal Silicon Dioxide, Iron Oxide Yellow, Lactose, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Sodium Starch Glycolate, Titanium Dioxide, and the following:

**15 mg** tablets also contain: Hydroxypropyl Methylcellulose, Polysorbate 80

**30 mg** tablets also contain: Iron Oxide Red, Polyvinyl Alcohol, Talc

**What dosage forms it comes in:**

**Tablets:** 15 mg and 30 mg

**WARNINGS AND PRECAUTIONS**

**During treatment with these types of medications, it is important that you and your doctor have good ongoing communication about how you are feeling.**

**PRO-MIRTAZAPINE is not for use in children under 18 years of age.**

**Changes in Feelings and Behaviour:**

It is important that you have good communication with your doctor about how you feel. Discussing your feelings and treatment with a friend or relative who can tell you if they think you are getting worse is also useful.

Some patients may feel worse when first starting or changing the dose of drugs such as PRO-MIRTAZAPINE. You may feel more anxious or may have thoughts of hurting yourself or others, especially if you have had thoughts of hurting yourself before. These changes in feelings can happen in patients treated with drugs like PRO-MIRTAZAPINE for any condition, and at any age, although it may be more likely if you are aged 18 to 24 years old. If this happens, see your doctor immediately. Do not stop taking PRO-MIRTAZAPINE on your own.

**BEFORE you use PRO-MIRTAZAPINE, talk to your doctor or pharmacist:**

- if you have ever had an allergic reaction to any medication;
- if you have QT/QTc prolongation or a family history of QT/QTc prolongation;
- if you have heart disease;
- about all your medical conditions, including a history of seizures, liver or kidney disease, heart problems, such as certain kinds of heart conditions that may change your heart rhythm, a recent heart attack, heart failure, or take certain medicines that may affect the heart's rhythm, diabetes, low blood pressure, glaucoma (increased intra-ocular pressure), high cholesterol and/or high triglycerides (fats in the blood), difficulties in urinating as a result of an enlarged prostate, psychiatric diseases such as schizophrenia and bipolar disorder (alternating periods of elation/overactivity and depressed mood);
- about any medications (prescription or non-prescription) you are taking (refer to the next section for specific interactions with PRO-MIRTAZAPINE);
- about any natural or herbal products you are taking (e.g., St. John's Wort);
- if you are pregnant or thinking of becoming pregnant, or if you are breastfeeding;
- about your habits of alcohol consumption;
- if you have hereditary galactose intolerance or glucose-galactose malabsorption.

PRO-MIRTAZAPINE is not for use in children under 18 years of age.

Refrain from potentially hazardous tasks, such as driving a car or operating dangerous machines, until you are certain that this medication does not affect your mental alertness or physical coordination.

Contact your physician before stopping or reducing your dosage of PRO-MIRTAZAPINE. Symptoms such as dizziness, abnormal dreams, electric shock sensations, agitation, anxiety, difficulty concentrating, headache, tremor, nausea, vomiting, sweating or other symptoms may occur after stopping or reducing the dosage of PRO-MIRTAZAPINE. Such symptoms may also occur if a dose is missed. 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 PRO-MIRTAZAPINE to alleviate these symptoms.

**Effects on Pregnancy and Newborns**

**If you are already taking/using PRO-MIRTAZAPINE 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.**

**Possible complications at birth (from taking any newer antidepressant, including PRO-MIRTAZAPINE):**

Post-marketing reports indicate that some newborns whose mothers took an SSRI (Selective Serotonin Reuptake Inhibitor) or other newer anti-depressants, such as PRO-MIRTAZAPINE, during pregnancy have developed complications at birth requiring prolonged hospitalization, breathing support and tube feeding. Reported symptoms include: feeding and/or breathing difficulties, seizures, tense or overly relaxed muscles, jitteriness and constant crying. In most cases, the newer anti-depressant was taken during the third trimester of pregnancy. These symptoms are consistent with either a direct adverse effect of the anti-depressant on the baby, or possibly a discontinuation syndrome caused by sudden withdrawal from the drug. These symptoms normally resolve over time. However, if your baby experiences any of these symptoms, contact your doctor as soon as you can.

If you are pregnant, or nursing, and taking an SSRI or other newer anti-depressants, such as PRO-MIRTAZAPINE, you should discuss the risks and benefits of the various treatment options with your doctor. It is very important that you do NOT stop taking these medications without first consulting your doctor. See also SIDE EFFECTS AND WHAT TO DO ABOUT THEM section.

**INTERACTIONS WITH THIS MEDICATION**

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| <p><b>Serious Drug Interactions</b></p> <p><b>Do not use PRO-MIRTAZAPINE if you are taking or have recently taken:</b></p> <ul style="list-style-type: none"> <li>• Monoamine oxidase inhibitor (e.g., phenelzine, tranylcypromine, moclobemide, selegiline, linezolid, methylene blue)</li> <li>• Thioridazine</li> <li>• Pimozide</li> </ul> |
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**You should tell your doctor if you are taking or have recently taken any medications (prescription, non-prescription or natural/herbal), especially:**

- other antidepressants, such as SSRIs, venlafaxine and certain tricyclics
- other drugs that affect serotonin such as tryptophan, triptans, lithium, tramadol, methylene blue (used to treat high levels of methemoglobin in the blood), St. John’s Wort
- ketoconazole (medicine for treating fungal infections)
- cimetidine (used to treat reflux and stomach ulcers)
- erythromycin [used to treat bacterial infections (antibiotic)]
- drugs used to treat Human Immunodeficiency Virus (HIV), such as a combination of fosamprenavir and ritonavir
- nefazodone (used to treat depression)
- certain drugs used to treat epilepsy, such as carbamazepine and phenytoin
- rifampicin (used to treat tuberculosis)
- warfarin (used to prevent blood clotting)
- benzodiazepines (e.g., midazolam, oxazepam and diazepam) – as PRO-MIRTAZAPINE may add to the sedative effects of these agents.
- medicines that may affect the heart’s rhythm such as certain antibiotics and some anti-psychotics.

Avoid alcoholic drinks while taking PRO-MIRTAZAPINE

**PROPER USE OF THIS MEDICATION**

**Usual adult dose:**

It is very important that you take PRO-MIRTAZAPINE exactly as your doctor has instructed. Generally, most people take between 15 mg and 45 mg per day.

**How to take PRO-MIRTAZAPINE:**

- Never increase or decrease the amount of PRO-MIRTAZAPINE you, or those in your care if you are a caregiver or guardian, are taking unless your doctor tells you to, and do not stop taking this medication without consulting your doctor (see Warnings and Precautions when taking PRO-MIRTAZAPINE).
- Some symptoms may begin to improve within about two weeks, but significant improvement can take several weeks. Continue to follow the doctor’s instructions.
- The tablets should be taken at the same time each day, preferably as a single evening dose (prior to sleep). Do not chew them.
- Keep taking your tablets until the doctor tells you to stop. The doctor may tell you to take your medicine for several months. Continue to follow the doctor’s instructions.
- Do not take a double dose to make up for forgotten doses.

- If you forget to take your evening dose, do not take the missed dose the next morning. Continue treatment in the evening (prior to sleep) with your normal dose.

**Overdose:**

If you think you have taken too much PRO-MIRTAZAPINE, contact a healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

The most likely signs of an overdose of PRO-MIRTAZAPINE (without other medicines or alcohol) are drowsiness, disorientation and increased heart rate. The symptoms of a possible overdose may include changes to your heart rhythm (fast, irregular heartbeat) and/or fainting which could be symptoms of a life-threatening condition known as *torsade de pointes*.

**Missed Dose:**

Do not take a double dose to make up for forgotten doses. If you forget to take your evening dose, do not take the missed dose the next morning. Continue treatment in the evening (prior to sleep) with your normal dose.

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

Like other medications, PRO-MIRTAZAPINE can cause some side effects. You may not experience any of them. For most patients, side effects are likely to be minor and temporary. However, some may be serious. Some of these side effects may be dose-related. Consult your doctor if you experience these or other side effects, as the dose may have to be adjusted.

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

- The most common side effects (> 10%) include sleepiness, dry mouth, increased appetite, constipation and weight gain.
- Other side effects may include: tiredness (feeling weak), swelling (typically in ankles or feet), occasional dizziness or faintness (especially when you get up quickly from a lying or sitting position), itchiness, tremor (shakiness), abnormal dreams, rash, increased levels of fats in the blood, urinary tract infections, abnormal sensation in the skin (e.g., burning, stinging, tickling or tingly).

**Decrease in White Blood Cells**

If you experience sudden unexplainable signs of infection such as high fever, chills, sore throat and mouth or nose sores, tell your doctor right away. In rare cases, PRO-MIRTAZAPINE can cause a decrease in white blood cells, which are needed to fight infection.

**New or Worsened Emotional or Behavioural Problems**

A small number of patients taking drugs of this type may feel worse instead of better; for example, they may experience new or worsened feelings of agitation, hostility or anxiety, or thoughts about suicide. Your doctor should be informed of such changes

immediately. Close observation by a doctor is necessary in this situation. Do not discontinue your medication on your own. See also the WARNINGS AND PRECAUTIONS section.

**Discontinuation Symptoms**

Contact your doctor before stopping or reducing your dosage of PRO-MIRTAZAPINE. Symptoms such as dizziness, abnormal dreams, electric shock sensations, agitation, anxiety, difficulty concentrating, headache, tremor, nausea, vomiting, sweating and other symptoms have been reported after stopping PRO-MIRTAZAPINE. 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 PRO-MIRTAZAPINE to alleviate the symptoms. See WARNINGS AND PRECAUTIONS section for more information.

**Effects on Newborns**

Some newborns whose mothers took an SSRI or other newer antidepressants during pregnancy have shown such symptoms as breathing and feeding difficulties, jitteriness and constant crying. If your baby experiences any of these symptoms, contact your doctor as soon as you can. See WARNING AND PRECAUTIONS section for more information.

| SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN 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 |   |
| <b>Common</b>  |                                      |              |   |
| Drowsiness which can lead to impaired concentration, generally occurring during the first few weeks of treatment   | ✓                                    |              |   |
| Weight gain  | ✓                                    |              |   |
| <b>Infrequent</b>  |                                      |              |   |
| Aggression   |                                      |              | ✓   |
| <b>Rare</b>  |                                      |              |   |
| Bruising and/or unusual bleeding and symptoms of infection such as sudden high fever, sore throat, mouth ulcers, severe digestive system disturbances or other signs of infection (symptoms of blood cell disturbances). |                                      | ✓            |   |
| Convulsions (loss of consciousness with uncontrollable shaking)  |                                      |              | ✓   |
| Fainting/loss of consciousness   |                                      | ✓            |   |
| Nightmares/vivid dreams, agitation or confusion  |                                      | ✓            |   |

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN 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 |   |
| Hallucinations (strange visions or sounds)   |                                      | ✓            |   |
| Mania (excessive happiness or irritability, racing thoughts, greatly increased energy, severe trouble sleeping, reckless behaviour)  |                                      |              | ✓   |
| Akathisia (feeling restless and unable to stand still)   | ✓                                    |              |   |
| Uncontrolled, sudden movements   | ✓                                    |              |   |
| Restless legs (feeling of unrest during night mainly located in the legs combined with sudden muscle contractions in the legs)   | ✓                                    |              |   |
| Pain in the joints or muscles  |                                      | ✓            |   |
| Jaundice (yellowing of eyes or skin, dark urine)   |                                      |              | ✓   |
| Symptoms of depression (anxiety and disturbed sleep)   | ✓                                    |              |   |
| Severe skin reactions such as Stevens-Johnson syndrome (fever, rash, swollen lymph nodes, hives, sore mouth, sore eyes or swelling of lips or tongue)  |                                      |              | ✓   |
| Low sodium levels in blood (feeling ill with symptoms of weakness, drowsiness, confusion, combined with achy, stiff or uncoordinated muscles)  |                                      |              | ✓   |
| Abdominal pain and nausea; this may suggest inflammation of the pancreas (pancreatitis)  | ✓                                    |              |   |
| <b>Very Rare</b>   |                                      |              |   |
| “Serotonin toxicity” (a reaction which may cause feelings of agitation or restlessness, flushing, muscle twitching, involuntary eye movements, heavy sweating, high body temperature (> 38°C ), or rigid muscles). |                                      |              | ✓   |
| <b>See Warnings &amp; Precautions</b>  |                                      |              |   |
| Changes in feelings or behaviour (anger, anxiety, suicidal or violent thoughts)  |                                      |              | ✓   |

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN 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 |   |
| <b>Unknown</b>  |                                      |              |   |
| Abnormal heart rate or rhythm, palpitations, fainting   |                                      | ✓            |   |
| Rhabdomyolysis (very dark (“tea coloured”) urine, muscle tenderness and/or aching)  |                                      | ✓            |   |
| Increased prolactin hormone levels in blood (hyperprolactinemia, including symptoms such as enlarged breasts and/or milky nipple discharge) |                                      | ✓            |   |
| Sleepwalking  |                                      | ✓            |   |
| Prolonged painful erection of the penis   |                                      |              | ✓   |

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

**HOW TO STORE IT**

- Store between 15°C and 30°C. Protect from light
- Keep PRO-MIRTAZAPINE out of reach and sight of children.
- Do not use PRO-MIRTAZAPINE after the expiry date indicated on the package.

**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/adverse-reaction-reporting.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.*

**MORE INFORMATION**

**If you want more information about PRO-MIRTAZAPINE:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>) or by contacting Pro Doc Ltée at 1-800-361-8559, [www.prodoc.qc.ca](http://www.prodoc.qc.ca) or [info@prodoc.qc.ca](mailto:info@prodoc.qc.ca).

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