

PART III: CONSUMER INFORMATION

^{Pr}PRO-MIRTAZAPINE (mirtazapine tablets)

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 antidepressants

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:

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 important nonmedicinal 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 important nonmedicinal ingredients are:

15 mg Tablets: Each film coated tablet contains 15 mg of mirtazapine. Non medicinal ingredients (alphabetical): colloidal silicon dioxide, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, sodium starch glycolate, synthetic yellow iron oxide and titanium dioxide.

30 mg Tablets: Each film coated tablet contains 30 mg of mirtazapine. Non medicinal ingredients (alphabetical): colloidal silicon dioxide, iron oxide yellow, iron oxide red, lactose monohydrate, macrogol/PEG 3350, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol-part. hydrolyzed, sodium starch glycolate, talc and titanium dioxide.

What dosage forms it comes in:

PRO-MIRTAZAPINE

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.

New or Worsened Emotional or Behavioural Problems

Particularly in the first few weeks of treatment, or when doses are adjusted, a small number of patients taking drugs of this type may feel worse instead of better; for example, they may experience unusual feelings of agitation, hostility or anxiety, or have impulsive or disturbing thoughts such as thoughts of self-harm or harm to others. Should this happen to you, or to those in your care if you are a caregiver or guardian, consult your doctor immediately; Close observation by a doctor is necessary in this situation. **Do not discontinue your medication on your own.**

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

- about all your medical conditions, including a history of seizures, liver or kidney disease, heart problems, 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 nonprescription) 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

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.

- 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.

Avoid alcoholic drinks while taking PRO-MIRTAZAPINE

PROPER USE OF THIS MEDICATION

Usual 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:

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.

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.

INTERACTIONS WITH THIS MEDICATION

Do not use PRO-MIRTAZAPINE if you are taking or have recently taken monoamine oxidase inhibitors (e.g., phenelzine, moclobemide, tranylcypromine, selegeline, linezolid, methylene blue), thioridazine, or pimozide.

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, 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

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.

- You may experience some side effects, such as increase in appetite, swollen ankles or feet, occasional dizziness or faintness (especially when you get up quickly from a lying or sitting position), nausea and headache.
- In rare cases, other effects may include rash, abnormal sensation in the skin (e.g., burning, stinging, tickling or tingly), blood cells, involuntary trembling of muscles (tremor), dry mouth, tiredness.
- In very rare cases, other effects may include abnormal sensations in the mouth, sensations of numbness in the mouth and swelling in the mouth. Some side effects are temporary. Consult your doctor if you experience these or other side effects, as the dose may have to be adjusted.

Decrease in White Blood Cells

If you experience signs of infection such as sudden unexplainable 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.

Symptom/effect	Talk with your doctor or pharmacist		Seek immediate emergency medical assistance
	Only if severe	In all cases	
Common	Drowsiness which can lead to impaired concentration, generally occurring during the first few weeks of treatment	√	
	Weight gain	√	
Rare	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		√
	Hallucinations (strange visions or sounds)		√
	Mania (feeling elated or emotionally 'high')		√
	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)		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom/effect		Talk with your doctor or pharmacist		Seek immediate emergency medical assistance
		Only if severe	In all cases	
Rare	Low sodium levels in blood (feeling ill with symptoms of weakness, drowsiness, confusion, combined with achy, stiff or uncoordinated muscles)			√
Very Rare See WARNINGS & PRECAUTIONS	A combination of symptoms such as unexplainable fever, sweating, increased heart rate, diarrhea, (uncontrollable) muscle contractions, shivering, overactive reflexes, restlessness, mood changes and unconsciousness (can be signs of serotonin syndrome)			√
	New or worsened emotional or behavioral problems			√

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 at controlled room temperature, 15°C - 30°C, protect from light
- Keep PRO-MIRTAZAPINE out of the reach and sight of children.
- Do not use PRO-MIRTAZAPINE after the expiry date indicated on the package

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 0701D
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 more information, please contact your doctor, pharmacist or other healthcare professional.

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting

Pro Doc Ltée at 1-800-361-8559, <http://www.prodoc.qc.ca> or info@prodoc.qc.ca.

This leaflet was prepared by Pro Doc Ltée, Laval, Québec, H7L 3W9

Date of Revision: November 25, 2011