PART III: CONSUMER INFORMATION

[Pr]PRO-FLUOXETINE
(Fluoxetine Hydrochloride)
Capsules

This leaflet is part III of a three-part "Product Monograph" published when PRO-FLUOXETINE 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-FLUOXETINE. Contact your doctor or pharmacist if you have any questions about the drug.

Please read this information before you start to take your medicine, even if you have taken this drug before. Keep this information with your medicine in case you need to read it again.

ABOUT THIS MEDICATION

What the medication is used for:
PRO-FLUOXETINE has been prescribed by your doctor to relieve your symptoms of:
- depression (feeling sad, a change in appetite or weight, difficulty concentrating or sleeping, feeling tired, headaches, unexplained aches and pain)
- bulimia (eating disorder, characterized by self-induced vomiting after eating)
- or obsessive-compulsive disorder (recurrent and intrusive thought, feeling, idea, or sensation; recurrent pattern of behaviour, or unwanted thoughts or actions)

What it does:
PRO-FLUOXETINE (fluoxetine hydrochloride) belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). PRO-FLUOXETINE is thought to work by increasing the levels of a chemical in the brain called serotonin (5-hydroxytryptamine).

When it should not be used:
Do not use PRO-FLUOXETINE if you are:
- allergic to it or any of the components of its formulation (see What the nonmedicinal ingredients are:).
- currently or have recently taken the drug thioridazine.
- currently or have recently taken monamine oxidase anti-depressants (e.g. phenelzine sulphate, moclobemide).

What the medicinal ingredient is:
fluoxetine hydrochloride.

What the nonmedicinal ingredients are:
colloidal silicon dioxide, D&C Yellow No.10, FD&C Blue No. 1, FD&C Yellow No. 6, gelatin, starch and titanium dioxide. Additionally, the 10 mg capsule also contains: iron oxide black.

What dosage forms it comes in:
Capsules: 10 mg and 20 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-FLUOXETINE is not for use in children under 18 years of age.

New or Worsened Emotional or Behavioural Problems
Particularly in the first few weeks or when doses are adjusted, 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, impulsivity, or thoughts about suicide, self-harm 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 those in your care, **consult 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.

PRO-FLUOXETINE has an effect on the electrical activity of the heart
In very rare cases, this effect can lead to disturbances in heart rhythm. These heart rhythm disturbances are more likely in patients with risk factors, such as heart disease, or in the presence of certain drugs. In general, females and people more than 65 years in age are at higher risk. It is important to follow the instructions of your doctor with regard to dosing. If you experience any symptoms of a possible heart rhythm disturbance, such as dizziness, palpitations (sensation of rapid, pounding, or irregular heart beat), fainting, or seizures, you should seek immediate medical attention.

Before starting PRO-FLUOXETINE, tell your doctor or pharmacists:
- 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 a heart disease;
- if you have a personal history of fainting spells;
- if you have a family history of sudden cardiac death at <50 years;
- if you have electrolyte disturbances (e.g., low blood potassium or magnesium levels) or conditions that could lead to electrolyte disturbances (e.g., vomiting, diarrhea, dehydration);
- if you use diuretics, enemas and/or laxatives;

- all your medical conditions, including a history of liver or kidney problems, seizures or blackouts, diabetes, bleeding disorder or have been told that you have low platelets, glaucoma or increased pressure in the eyes, eye pain, or blurred vision;
- if you had a recent bone fracture or were told you have osteoporosis or risk factors for osteoporosis.
- any medications (prescription or nonprescription) you are taking or have recently taken, especially monoamine oxidase (MAO) inhibitors (e.g., phenelzine sulfate, tranylcypromine sulfate, moclobemide or selegeline) or thioridazine or anticoagulants, acetylsalicylic acid (ASA) and other non-steroidal anti-inflammatory drugs (e.g., ibuprofen);
- any natural or herbal products you are taking (e.g. St. John's Wort);
- if you are pregnant or thinking about becoming pregnant, or if you are breast feeding;
- 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
If you are already taking PRO-FLUOXETINE and have just found out that you are pregnant, you should talk to your doctor as soon as possible.

Taking PRO-FLUOXETINE in early stages of pregnancy:
Some studies have suggested a small increased risk of birth defects affecting the heart in babies whose mothers took PRO-FLUOXETINE during the first few months of pregnancy. In the general population, about 1 in 100 babies are born with a heart defect. The studies found that this increased to about 2 in 100 babies whose mothers took PRO-FLUOXETINE during early pregnancy.

Taking PRO-FLUOXETINE in later stages of pregnancy:

Possible complications at birth (from taking any newer antidepressant, including PRO-FLUOXETINE):
Post-marketing reports indicate that some newborns whose mothers took an SSRI (selective serotonin reuptake inhibitor) or other newer anti-depressant during pregnancy have developed complications at birth requiring prolonged hospitalization, breathing support and tube feeding. Reported symptoms included 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.

Persistent Pulmonary Hypertension (PPHN) and newer antidepressants:
The use of SSRIs, including PRO-FLUOXETINE, during late pregnancy, may increase the risk of a serious lung condition called persistent pulmonary hypertension of the newborn (PPHN) that causes breathing difficulties in newborns soon after birth. In the general population, PPHN is known to occur in about 1 or 2 per 1000 newborns but this may be increased 2 to 6 times in babies whose mothers used SSRIs during late pregnancy.

If you are pregnant and taking an SSRI, or other newer anti-depressant, 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 SIDE EFFECTS AND WHAT TO DO ABOUT THEM section for more information.

Taking PRO-FLUOXETINE 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

Serious Drug Interactions
Do not use PRO-FLUOXETINE if you are taking or have recently taken
- Monoamine oxidase inhibitors (e.g., phenelzine, tranylcypromine, moclobemide or selegiline, linezolid, methylene blue)
- Thioridazine.

You should tell your doctor if you are taking or have recently taken any medications (prescription, nonprescription or natural/herbal), especially:
- other anti-depressants, such as SSRIs, certain tricylics, drugs used to treat schizophrenia, or bipolar depression (e.g. lithium)
- anti-infectives
- cancer drugs
- asthma drugs
- drugs to treat nausea and vomiting
- painkillers
- diuretics
- 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 patients with irregular heart beats (antiarrhythmics)
- certain drugs used to treat diabetes
- other drugs that affect serotonin, such as lithium, linezolid, drugs containing tryptophan, St. Johns 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 used to treat cough, such as dextromethorphan
- sedatives such as benzodiazapines.

As with many drugs that work directly on the brain, use of alcohol while taking PRO-FLUOXETINE should be limited/moderate.

PROPER USE OF THIS MEDICATION

Usual dose:

- It is very important that you take PRO-FLUOXETINE exactly as your doctor has instructed. Generally people take between 20 mg to 80 mg per day for depression and obsessive-compulsive disorder and between 20 and 60 mg per day for bulimia.
- PRO-FLUOXETINE is usually taken once a day. It may be taken with or without food. If you are taking capsules, you should swallow the capsules whole; do not chew them.
- You should continue to take your medicine even if you do not feel better, as it may take a number of weeks for your medicine to work.
- Keep taking your PRO-FLUOXETINE until the doctor tells you to stop.
- Talk to your doctor before you stop taking your medication on your own.

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.

Missed Dose
If you forget to take a dose of PRO-FLUOXETINE, take it as soon as you remember. Take your next dose at the next scheduled time; do not try to make up for a missed dose by taking a double dose the next time.

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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like other medications, PRO-FLUOXETINE 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.
The most common side effects of PRO-FLUOXETINE are:

- nausea
- dizziness
- headache
- anxiety
- nervousness
- drowsiness
- insomnia (difficulty falling or staying asleep)
- fatigue
- weakness
- diarrhea
- upset stomach
- dry mouth
- loss of appetite
- excessive sweating

PRO-FLUOXETINE does not usually affect people's normal activities. However, some people feel sleepy while taking it, in which case they should not drive or operate machinery.

Although psychiatric disorders may be associated with decreases in sexual desire, performance and satisfaction, treatment with this medication may also affect sexual functioning. Occasionally, these symptoms may continue after stopping PRO-FLUOXETINE.

PRO-FLUOXETINE can raise your levels of a hormone called "prolactin" (measured with a blood test). Symptoms of high prolactin may include:
In men: breast swelling, difficulty in getting or maintaining erections, or other sexual dysfunction.
In women: breast discomfort, leakage of milk from the breasts, missed menstrual periods, or other problems with your cycle.

If you experience any symptoms of a possible heart rhythm disturbance, such as dizziness, palpitations, fainting or seizures, you should seek immediate medical attention.

Discontinuation Symptoms
Contact your doctor before stopping or reducing your dosage of PRO-FLUOXETINE. Symptoms such as headache, insomnia, paresthesias (numbness, tingling, burning, or prickling sensation) nervousness, anxiety, nausea, sweating, dizziness, jitteriness and weakness and other symptoms have been reported after stopping PRO-FLUOXETINE. 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-FLUOXETINE to alleviate the symptoms. See WARNINGS AND PRECAUTIONS section for more information.

Effects on Newborns
Some newborns whose mothers took an SSRI (Selective Serotonin Uptake Inhibitor) 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 with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Common	Allergic reactions (red skin, hives, swelling of the lips, face, tongue, throat, trouble breathing, wheezing, shortness of breath, skin rashes, blisters of the skin, sores or pain in the mouth or eyes)			✓
	Allergic reactions (skin rash, hives alone)		✓	
Unknown	Low Platelets: Bruising or unusual bleeding from the skin or other areas		✓	
Uncommon	Hallucinations [strange visions or sounds]		✓	
	Inability to urinate		✓	
	Akathisia [feeling restless and unable to sit or stand still]		✓	
	Seizures [i.e. loss of consciousness with uncontrollable shaking ("fit")]			✓
	Mania [overactive behaviour and thoughts]		✓	
Rare	Gastrointestinal bleeding [vomiting blood or passing blood in stools]			✓
	Glaucoma: Increased pressure in the eyes [symptoms of eye pain and blurred vision]		✓	
	Liver disorder [symptoms include nausea, vomiting, loss of appetite combined with itching, yellowing of the skin or eyes, dark urine]		✓	
	Uncontrollable movements of the body or face		✓	
	Low sodium level in blood [symptoms of tiredness, weakness, confusion combined with achy, stiff or uncoordinated muscles]		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Very Rare	Serotonin syndrome [a combination of most or all of the following; confusion, restlessness, sweating, shaking, shivering, hallucinations, sudden jerking of the muscles, fast heartbeat]			✓
See Warnings & Precautions	New or worsened emotional or behavioural problems		✓	

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

HOW TO STORE IT

Keep all medicines out of the reach of children. PRO-FLUOXETINE should be stored in its original package between 15°C and 30°C, in a dry place and out of direct sunlight. The expiry date of this medicine is printed on the package label. Do not use the medicine after the expiry date. If your doctor tells you to stop taking PRO-FLUOXETINE or you find that they have passed their expiry date, please return any left over medicine to your pharmacist.

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

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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

Last revised: June 16, 2014