

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

#### **Pr PRO-FLUOXETINE**

#### **Fluoxetine Capsules, USP**

Read this carefully before you start taking **PRO-FLUOXETINE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PRO-FLUOXETINE**.

#### **What is PRO-FLUOXETINE used for?**

PRO-FLUOXETINE is used 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 (an eating disorder where you force yourself to vomit after eating)
- Obsessive-compulsive disorder (recurrent and intrusive thoughts, feelings, ideas, or sensations; recurrent pattern of behaviour, or unwanted thoughts or actions)

#### **How does PRO-FLUOXETINE work?**

PRO-FLUOXETINE 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. This helps to relieve your symptoms of depression, bulimia and/or obsessive-compulsive disorder.

#### **What are the ingredients in PRO-FLUOXETINE?**

Medicinal ingredients: fluoxetine hydrochloride.

Non-medicinal ingredients: Colloidal Silicon Dioxide, D&C Yellow No.10, FD&C Blue No. 1, FD&C Yellow No. 6, Gelatin, Pregelatinized Starch and Titanium Dioxide.

Additionally, the 10 mg capsule also contains: Iron Oxide Black.

#### **PRO-FLUOXETINE comes in the following dosage forms:**

Capsules; 10 mg and 20 mg

#### **Do not use PRO-FLUOXETINE if:**

- you are allergic to fluoxetine hydrochloride or to any of the non-medicinal ingredients in PRO-FLUOXETINE (see What are the ingredients in PRO-FLUOXETINE:).
- you are currently or have recently taken the drug thioridazine.
- you are currently or have recently taken any monamine oxidase anti-depressants such as phenelzine sulphate, moclobemide, linezolid. If you are unsure, ask your healthcare professional.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PRO-FLUOXETINE. Talk about any health conditions or problems you may have, including if you:**

- have anorexia
- have bipolar disorder
- have ever had an allergic reaction to any medication

- have QT/QTc prolongation or a family history of QT/QTc prolongation
- have a heart disease
- have a personal history of fainting spells
- have a family history of sudden cardiac death at less than 50 years of age
- have electrolyte disturbances (e.g., low blood potassium or magnesium levels) or conditions that could lead to electrolyte disturbances (e.g., vomiting, diarrhea, dehydration)
- have or have a history of a bleeding disorder or have been told that you have low platelets
- have or have a history of liver or kidney problems
- have or have a history of seizures
- have diabetes
- had a recent bone fracture or were told you have osteoporosis or risk factors for osteoporosis
- are pregnant, thinking about becoming pregnant, or if you are breast feeding
- drink alcohol and /or use street drugs

**Other warnings you should know about:**

**During treatment with PRO-FLUOXETINE, it is important that you and your doctor talk regularly about how you are feeling.**

**Do NOT stop taking PRO-FLUOXETINE without talking to your healthcare professional first, as it may cause unwanted side effects such as headache, insomnia, numbness, tingling, burning, or prickling, nervousness, anxiety, nausea, sweating, dizziness, jitteriness, and weakness.**

**New or worsened emotional or behavioural problems:** When you first start taking PRO-FLUOXETINE or when your dose is adjusted, you may feel worse instead of better. You may feel new or worsened feelings of agitation, hostility, anxiety, or impulsivity, Do NOT stop taking your medicine, it takes time for PRO-FLUOXETINE to work.

**Self-harm:** If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital **right away**. You may find it helpful to tell a relative or close friend that you are depressed or have other mental illnesses. Ask them to read this leaflet. You might ask them to tell you if they:

- think your depression or mental illness is getting worse, or
- are worried about changes in your behaviour

**Pregnancy:** Only take PRO-FLUOXETINE during pregnancy if you and your doctor have discussed the risks and have decided that you should. If you take PRO-FLUOXETINE near the end of your pregnancy, you may be at a higher risk of heavy vaginal bleeding shortly afterbirth. If you become pregnant while taking PRO-FLUOXETINE, tell your doctor **right away**.

**Effects on newborns:** In some cases, babies born to a mother taking PRO-FLUOXETINE during pregnancy may require hospitalization, breathing support and tube feeding. Be ready to seek medical help for your newborn if they:

- Have trouble breathing or feeding,
- Have muscle stiffness, or floppy muscles (like a rag doll)
- Have seizures (fits)
- Are shaking (jitteriness)
- Are constantly crying

If you take PRO-FLUOXETINE:

- During early pregnancy, there is a possible slight increased risk that your newborn may have a heart defect.
- During late pregnancy, your newborn may be at risk of having a serious lung condition called Persistent Pulmonary Hypertension of the Newborn (PPHN), which causes breathing problems.

**Falls:** PRO-FLUOXETINE can cause you to feel sleepy or dizzy and can affect your balance. This increases your risk of falling, which can cause fractures or other fall related-injuries, especially if you:

- Take sedatives
- Consume alcohol
- Are elderly
- Have a condition that causes weakness or frailty

**Driving and using machines:** PRO-FLUOXETINE may make you feel sleepy. Give yourself time after taking PRO-FLUOXETINE to see how you feel before driving a vehicle or using machinery.

**PRO-FLUOXETINE can cause serious side effects including:**

- Angle-closure glaucoma (sudden eye pain)
- Heart rhythm problems

See the **Serious side effects and what to do about them** table below for more information on these and other serious side effects.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with PRO-FLUOXETINE:**

<b>Serious Drug Interactions</b>
<p><b>Do not use PRO-FLUOXETINE 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 or selegiline, linezolid, methylene blue)</li><li>• Thioridazine</li></ul>

- drugs that affect how your heart beats such as quinidine, procainamide, disopyramide, amiodarone, sotalol, ibutilide, dronedarone, flecainide, propafenone
- drugs used to manage psychosis (antipsychotics) such as chlorpromazine, pimozide, haloperidol, droperidol, ziprasidone, clozapine
- drugs used to treat depression such as citalopram, venlafaxine, amitriptyline, imipramine, maprotiline, desipramine
- opioids and pain killers such as methadone, tramadol, fentanyl, tapentadol, meperidine, pentazocine
- drugs to treat bacterial infections such as erythromycin, clarithromycin, telithromycin, tacrolimus, moxifloxacin, levofloxacin, ciprofloxacin
- drugs used to treat fungal infections such as ketoconazole, fluconazole, voriconazole
- drugs used to treat malaria such as quinine, chloroquine

- drugs used to treat nausea and vomiting such as domperidone, dolasetron, ondansetron
- drugs used in cancer therapy such as vandetanib, sunitinib, nilotinib, lapatinib, vorinostat, tamoxifen
- drugs used to treat asthma such as salmeterol, formoterol
- drugs that affect your electrolyte levels such as diuretics (“water pills”), laxatives and enemas, amphotericin B, high dose corticosteroids (drugs that reduce inflammation)
- drugs that can affect how your blood clots such as warfarin, acetylsalicylic acid (Aspirin), non-steroidal anti-inflammatory drugs (NSAIDs)
- lithium, a drug used to treat bipolar disorder
- benzodiazepines such as diazepam, alprazolam
- drugs used to treat seizures such as carbamazepine, phenytoin
- drugs used to treat cough such as dextromethorphan
- tryptophan, a drug used to treat anxiety or used as a sleep aid
- sumatriptan, a drug used to treat migraines
- herbal medicines such as St. John’s Wort
- alcohol

**How to take PRO-FLUOXETINE:**

- It is very important that you take PRO-FLUOXETINE exactly as your doctor has instructed.
- PRO-FLUOXETINE may be taken with or without food.
- Swallow the capsules whole; do not chew or open them.
- Continue to take your medicine even if you do not feel better, as it may take a number of weeks for your medicine to start working.
- Keep taking your PRO-FLUOXETINE until the doctor tells you to stop.

**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.**

**Usual dose:**

**Depression**

Usual initial dose: 20 mg a day in the morning. Maximum dose: 60 mg a day.

**Bulimia**

60 mg a day.

**Obsessive-Compulsive Disorder**

20 mg to 60 mg a day.

**Overdose:**

If you think you, or a person you are caring for, have taken too much PRO-FLUOXETINE UOXETINE, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you forget to take a dose of PRO-FLUOXETINE, take it as soon as you remember. If it is almost time to take your next dose, skip the missed dose and take your next dose at the scheduled time. Do not try to make up for a missed dose by taking a double dose the next time.

**What are possible side effects from using PRO-FLUOXETINE?**

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

- nausea
- dizziness
- headache
- anxiety
- nervousness
- drowsiness
- insomnia (difficulty falling or staying asleep)
- fatigue
- weakness
- tremors (shaking)
- light-headedness
- diarrhea
- upset stomach
- indigestion
- dry mouth
- loss of appetite
- excessive sweating
- rash or itchy skin
- low sex drive
- weight gain or loss

Serious side effects 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>			
<b>Allergic Reaction:</b> difficulty swallowing or breathing, wheezing, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat.			✓
<b>Allergic reactions</b> (skin rash, hives alone)		✓	
<b>Anorexia</b> (an eating disorder): extremely low body weight, not eating, obsession with food, calories and dieting, excessive exercise		✓	
<b>UNCOMMON</b>			
<b>Akathisia</b> (a type of movement disorder): feeling restless, unable to sit or stand still		✓	
<b>Hallucinations</b> (seeing or hearing things that are not there)		✓	
<b>Mania:</b> elevated or irritable mood, decreased need for sleep, racing thoughts		✓	

<b>Seizures</b> (fits): uncontrollable shaking with or without loss of consciousness			✓
<b>Urinary retention</b> (inability to pass urine or to empty the bladder): pain		✓	
<b>RARE</b>			
<b>Angle-closure glaucoma</b> (sudden eye pain): increased pressure in your eyes, eye and head pain, swelling or redness in or around the eye, hazy or blurred vision, sudden loss of sight			✓
<b>Gastrointestinal Bleeding</b> (bleeding in the stomach or bowels): black, tarry stool, blood in the stool			✓
<b>Heart rhythm problems:</b> dizziness, palpitations (rapid, pounding, or irregular heartbeat), fainting or seizures			✓
<b>Hyponatremia</b> (low sodium in the blood): lethargy, confusion, muscular twitching, achy, stiff or uncoordinated muscles, seizure, coma		✓	
<b>Liver Disorder:</b> yellowing of the skin or eyes, dark urine and pale stools, abdominal pain, nausea, vomiting, loss of appetite		✓	
Uncontrollable movements of the body or face		✓	
<b>VERY RARE</b>			
<b>Serotonin Syndrome:</b> agitation, hallucinations, confusion, or other changes in mental status; coordination problems, uncontrolled muscle spasms, or muscle twitching (overactive reflexes); restlessness, shivering, racing or fast heartbeat, high or low blood pressure, sweating or fever, nausea, vomiting, or diarrhea, stiff muscles, tremor, loss of muscle control			✓
<b>UNKNOWN</b>			
<b>Increase in the hormone prolactin:</b> In women: breast discomfort, leakage of milk from the breasts, missed periods, or other problems with your menstrual cycle. In men: decreased body and facial hair, breast swelling, difficulty in getting or maintaining erections, or other sexual dysfunction		✓	
New or worsened emotional or behavioural problems		✓	
<b>Thrombocytopenia</b> (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### **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.*

### **Storage:**

- Store PRO-FLUOXETINE in its original package at room temperature (15°C to 30°C). Keep bottle tightly closed.
- Do not use the medicine after the expiry date printed on the package label.
- If your doctor tells you to stop taking PRO-FLUOXETINE or you find that the capsules have passed their expiry date, please return any left over medicine to your pharmacist.

Keep out of reach and sight of children.

### **If you want more information about PRO-FLUOXETINE:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); 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)

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

Last Revised: April 19, 2022