## IMPORTANT: PLEASE READ

**PART III: CONSUMER INFORMATION**

**PrFLUOXETINE**
**USP**
**(Fluoxetine Hydrochloride)**

**This leaflet is part III of a three-part "Product Monograph" published when 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 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:**
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)
- **Obsessive-compulsive disorder** (recurrent and intrusive thought, feeling, idea, or sensation; recurrent pattern of behaviour, or unwanted thoughts or actions)

**What it does:**
FLUOXETINE (fluoxetine hydrochloride) belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). 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 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.
- are currently or have recently taken monamine oxidase anti-depressants (e.g. phenelzine sulphate, moclobemide).

**What the medicinal ingredient is:**
FLUOXETINE capsules contain the active ingredient fluoxetine hydrochloride.

**What the nonmedicinal ingredients are:**
FLUOXETINE 10 mg capsules contain: fluoxetine hydrochloride equivalent to 10 mg of fluoxetine, pregelatinized starch, sodium starch glycolate, colloidal silicon dioxide, and magnesium stearate. The capsule shell contains gelatin, sodium lauryl sulfate, silicon dioxide, titanium dioxide, iron oxide black, FD & C yellow #6, FD& C blue #1, and D & C yellow # l0.

FLUOXETINE 20 mg capsules contain: fluoxetine hydrochloride equivalent to 20 mg of fluoxetine, pregelatinized starch, sodium starch glycolate, colloidal silicon dioxide, and magnesium stearate. The capsule shell contains gelatin, sodium lauryl sulfate, silicon dioxide, titanium dioxide, FD & C yellow # 6, FD & C blue #1 and D & C yellow # 10.

There is no gluten, lactose, sulfite, or tartrazine in FLUOXETINE.

**What dosage forms it comes in:**
FLUOXETINE (fluoxetine hydrochloride) is available as:
10 mg: hard gelatin capsules with opaque green cap and opaque grey body, imprinted with black ink **novo** on cap and **10** on body containing 10 mg of fluoxetine. Bottles of 100.

20 mg: hard gelatin capsules with opaque light green cap and opaque ivory body, imprinted with black ink **novo** on cap, **20** on body, containing 20 mg of fluoxetine. Bottles of 100, 500.

## 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**.

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.

**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 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,
- 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 (e.g., Aspirin) and other non-steroidal anti-inflammatory drugs (e.g., ibuprofen)
- if you are taking tamoxifen (used to treat breast cancer)
- 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

**Angle-closure Glaucoma**
FLUOXETINE can cause an acute attack of glaucoma. Having your eyes examined before you take FLUOXETINE could help identify if you are at risk of having angle-closure glaucoma. Seek immediate medical attention if you experience:

- eye pain
- changes in vision
- swelling or redness in or around the eye.

**Effects on Pregnancy and Newborns**
If you are already taking FLUOXETINE and have just found out that you are pregnant, you should talk to your doctor as soon as possible.

**Taking 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 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 fluoxetine during early pregnancy.

**Taking fluoxetine in later stages of pregnancy:**

**Possible complications at birth (from taking any newer antidepressant, including 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 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 antidepressant, 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 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 FLUOXETINE if you are taking or have recently taken:**
- Monoamine oxidase inhibitor (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 (e.g. Aspirin) and other non-steroidal anti-inflammatory drugs (e.g. ibuprofen)
- tamoxifen, which is used to treat breast cancer
- 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 FLUOXETINE should be limited/moderate.

## PROPER USE OF THIS MEDICATION

- It is very important that you take FLUOXETINE exactly as your doctor has instructed.
- 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 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.**

**Usual adult dose:**

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

***Bulimia***
Recommended dose: 60 mg a day.

***Obsessive-Compulsive Disorder***
Dose range: 20 to 60 mg a day.

**Missed Dose:**
If you forget to take a dose of 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:**

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| 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 all other medications, 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 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

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 FLUOXETINE.

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 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 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 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 WARNINGS 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 | | Seek immediate emergency medical assistance |
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| | | Only if severe | In all cases | |
| Common | Allergic reactions [red skin, hives, itching, 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 | | ✓ | |
| Un-common | 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] | | | ✓ |
| | Angle-closure Glaucoma: eye pain , changes in vision and swelling or redness in or around the eye | | | ✓ |
| | Liver disorder [symptoms | | ✓ | |

| SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM | | | | |
|---|---|---|---|---|
| | 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] | | ✓ | |
| Very Rare | Serotonin syndrome [a combination of most or all of the following; confusion, restlessness, sweating, shaking, shivering, high fever, 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 FLUOXETINE, contact your doctor or pharmacist.*

## HOW TO STORE IT

Keep all medicines out of the reach and sight of children. FLUOXETINE in bottles should be stored between 15-30°C and protected from light. FLUOXETINE in Unit dose boxes should be kept between15-25°C and protected from high humidity and light.
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 FLUOXETINE or you find that they have passed their expiry date, please return any left over medicine to your pharmacist.

**Reporting Side Effects**

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

**3 ways to report**:

- Online at MedEffect (http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, ON
    K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php).

*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

This document plus the full product monograph, prepared for health professionals can be found by contacting Sanis Health Inc., at:
1-866-236-4076
Fax: 905-689-1465
or quality@sanis.com

## IMPORTANT: PLEASE READ

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