PART III: CONSUMER INFORMATION

PrCITALOPRAM – 20
PrCITALOPRAM – 40
Citalopram Tablets, USP

This leaflet is part III of a three-part "Product Monograph" published when CITALOPRAM was approved for sale in Canada and is designed specifically for Consumers. Please read this information before you start to take your medicine. Keep the leaflet while you are taking CITALOPRAM as you may want to read it again. This leaflet is a summary and will not tell you everything about CITALOPRAM. Contact your doctor or pharmacist if you have any questions about the drug. Always keep medicines out of the reach of children.

ABOUT THIS MEDICATION

What the medication is used for:
CITALOPRAM has been prescribed to you by your doctor 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:
CITALOPRAM belongs to a group of medicines known as antidepressants, more specifically to the family of medicines called SSRIs (Selective Serotonin Reuptake Inhibitors).

CITALOPRAM 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 CITALOPRAM at the same time as pimozide.
- Do not use CITALOPRAM if you are currently or have recently taken monoamine oxidase antidepressants (e.g. selegiline, moclobemide).
- Do not take CITALOPRAM if you are allergic to it, or to any of the components of its formulation (for list of ingredients see below).
- Stop taking CITALOPRAM and contact your doctor immediately if you experience an allergic reaction or any severe side effect.
- Do not use CITALOPRAM if you have been diagnosed with a congenital long QT syndrome

What the medicinal ingredient is:
citalopram hydrobromide

What the nonmedicinal ingredients are:
Croscarmellose sodium, hydroxyethyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol and titanium dioxide.

What dosage forms it comes in:
CITALOPRAM is available as 20 mg, or 40 mg tablets in unit dose and bottles.

WARNINGS AND PRECAUTIONS

Treatment with these types of medications is most safe and effective when you and your doctor have good communication about how you are feeling.

CITALOPRAM 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 inpatients 18 to 24 years old. Should this happen to you, or to 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.

Effects on Pregnancy and Newborns
If you are already taking/using CITALOPRAM 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 CITALOPRAM):
Post-marketing reports indicate that some newborns whose mothers took an SSRI (Selective Serotonin Reuptake Inhibitor) such as CITALOPRAM or other newer antidepressant during pregnancy have developed complications at birth requiring prolonged hospitalisation, 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 antidepressant was taken during the third trimester of pregnancy. These symptoms are consistent with either a direct adverse effect of the antidepressant 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 of the Newborn (PPHN) and newer antidepressants:
Preliminary information suggests that use of SSRIs during the second half of pregnancy may be associated with an increased rate of a serious lung condition called persistent pulmonary hypertension of the newborn (PPHN) that causes breathing difficulties in newborns soon after birth. According to the study, babies born with this condition were 6 times more likely than healthy babies to have been exposed to SSRIs. In the general population, PPHN is known to occur at a rate of about 1-2 per 1000 newborns.

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.

Risk of Bone Fractures:
Taking CITALOPRAM 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.

Before you use CITALOPRAM, tell your doctor or pharmacist:
- All your medical conditions, including heart problems, history of seizures, manic-depressive illness, liver or kidney disease or diabetes
- You have a bleeding disorder or have been told that you have low platelets.
- If you have QT/QTc prolongation or a family history of QT/QTc prolongation.
- 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, magnesium, or calcium levels) or conditions that could lead to electrolyte disturbances (e.g., vomiting, diarrhea, dehydration).
- If you have glaucoma or increased pressure in your eyes
- If you have an eating disorder or are following a strict diet.
- If you had a recent bone fracture or were told you have osteoporosis or risk factors for osteoporosis.
- If you are pregnant or thinking about becoming pregnant, or if you are breast feeding.
- Any medications (prescription or non-prescription) which you are taking or have taken within the last 14 days, especially monoamine oxidase inhibitors, pimozide, any other antidepressants, triptans used to treat migraines, lithium, tramadol or drugs containing tryptophan.
- Your habits of alcohol and /or street drug consumption.
- Any natural or herbal products you are taking (e.g. St. John's Wort.
- If you drive a vehicle or perform hazardous tasks during your work.

INTERACTIONS WITH THIS MEDICATION

Serious Drug Interactions

Do not use CITALOPRAM if you are taking or have recently taken:
- Monoamine oxidase inhibitor (e.g., phenelzine, tranylcypromine, moclobemide or selegiline)
- Pimozide
- Linezolid (an antibiotic)
- Methylene blue (intravenous)

The following list includes some, but not all, of the drugs that may increase the risk of side-effects while receiving CITALOPRAM. You should check with your doctor or pharmacist before taking any other medication (prescription, non-prescription or natural/herbal) with CITALOPRAM.

Other drugs that may interact with CITALOPRAM include:
- drugs to treat heart rhythm disturbances (antiarrhythmics)
- antipsychotics
- opioid painkillers
- drugs to treat infections
- drugs to treat nausea and vomiting
- cancer drugs

- asthma drugs
- diuretics (water pills)
- Carbamezepine
- Other SSRIs e.g., Cipralex® (escitalopram) or any other antidepressant (e.g., imipramine, desipramine)
- Lithium
- Tryptophan
- Cimetidine
- Triptans (e.g., sumatriptan, zolmitriptan, naratriptan)
- Fluconazole, Ketoconazole, Itraconazole
- Erythromycin
- Warfarin
- Omeprazole
- Any herbal product such as St. John's Wort
- Certain medicines which may affect blood clotting and increase bleeding, such as oral anticoagulants (e.g. warfarin, dabigatran), acetylsalicyIic acid (e.g. Aspirin) and other non-steroidal anti-inflammatory drugs (ibuprofen)
- 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.

Avoid drinking alcohol while taking CITALOPRAM.

Drugs from the class that CITALOPRAM belongs to may increase the chance of a bleeding event such as nose bleeds, bruising and even life threatening bleeding. This is more likely if you have a history of a bleeding disorder or are taking other drugs that are known to affect your platelets.

Treatment with an SSRI in patients with diabetes may alter glycaemic control (hypoglycaemia and hyperglycaemia).

Tell your doctor all the medicines (prescription or over the counter) and natural health products that you are using or thinking of taking.

PROPER USE OF THIS MEDICATION

Usual dose:

- It is important that you take CITALOPRAM exactly as your doctor has instructed.
  - Usually your doctor will prescribe 20 mg per day, which you will take once daily preferably at the same time each day. If you are elderly, your doctor may prescribe a lower dose. This dose may be increased. Never change the dose of CITALOPRAM you are taking, or that someone in your care is taking unless your doctor tells you to. Dosage directions should be followed carefully. Never exceed the prescribed dose.
- Swallow the tablets whole with a drink of water. Do not chew them. CITALOPRAM can be taken with or without food.
- You should continue to take CITALOPRAM even if you do not feel better, as it may take several weeks for your medication to work. Improvement may be gradual.
- Continue to take CITALOPRAM for as long as your doctor recommends it. Do not stop taking your tablets abruptly even if you begin to feel better, unless you are told to do so by your doctor. Your doctor may tell you to continue to take CITALOPRAM for several months. Continue to follow your doctor's instructions.

Overdose:

- If you have accidentally taken too much CITALOPRAM contact your doctor or the Regional Poison Control Centre immediately, even if you do not feel sick. If you go to the doctor or the hospital, take the CITALOPRAM container with you.

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:

If you forget a dose, take the next dose as planned. Do not take a double dose to make up for a forgotten dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

- CITALOPRAM may cause unwanted effects (side-effects). These may include fatigue, dry mouth, increased sweating, tremor (shakiness), nausea, diarrhea, somnolence (sleepiness), ejaculation disorder and upper respiratory tract infection.

- Contact your doctor before stopping or reducing your dosage of citalopram. Symptoms such as dizziness, abnormal dreams, electric shock sensations, agitation, anxiety, emotional indifference, difficulty concentrating, headache, migraine, tremor (shakiness), nausea, vomiting, sweating or other symptoms may occur after stopping or reducing the dosage of citalopram. 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 citalopram to reduce the symptoms.

- Side-effects are often mild and may disappear after a few days. If they are troublesome or persistent, or if you develop any other unusual side-effects while taking CITALOPRAM, please consult your doctor.
- Usually CITALOPRAM does not affect your ability to carry out normal daily activities. However, you should

not drive a car or operate machinery until you are reasonably certain that CITALOPRAM does not affect you adversely.

- Post-marketing reports indicate that some newborns whose mothers took an SSRI (Selective Serotonin Reuptake Inhibitor) such as CITALOPRAM or other newer antidepressant during pregnancy have developed complications at birth requiring prolonged hospitalisation, 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 antidepressant was taken during the third trimester of pregnancy. These symptoms are consistent with either a direct adverse effect of the antidepressant 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 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.

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

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

Symptom / effect		Talk with your doctor or pharmacist right away		Stop taking drug and seek immediate emergency medical assistance
		Only if severe	In all cases	
Uncommon	**Low Platelets:** Bruising or unusual bleeding from the skin or other areas		√	
	Mania: overactive behaviour and thoughts		√	

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

Symptom / effect		Talk with your doctor or pharmacist right away		Stop taking drug and seek immediate emergency medical assistance
		Only if severe	In all cases	
Rare	**Gastrointestinal bleeding:** Vomiting blood or passing blood in stools		√	
	Glaucoma: Increased pressure in the eye, eye pain and blurred vision		√	
	Low sodium level in blood: Symptoms of tiredness, weakness, confusion combined with achy, stiff or uncoordinated muscles		√	
	Serotonin Syndrome: A combination of symptoms, possibly including: agitation, confusion, tremor, sudden jerking of muscles, high fever			√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		**Talk with your doctor or pharmacist right away**		**Stop taking drug and seek immediate emergency medical assistance**
		Only if severe	**In all cases**	
Very Rare	**Liver disorder:** Symptoms include nausea, vomiting, loss of appetite combined with itching, yellowing of the skin or eyes, dark urine		√	
Very Rare	**Seizures:** Loss of consciousness with uncontrollable shaking ("fit")			√
See Warning & Precautions	**Akathisia:** Feeling restless and unable to sit or stand still		√	
	New or Worsened Emotional or Behavioural Problems		√	
Unknown	Abnormal heart rate or rhythm, palpitations, fainting		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		**Talk with your doctor or pharmacist right away**		**Stop taking drug and seek immediate emergency medical assistance**
		Only if severe	**In all cases**	
Unknown	**Signs of serious skin reactions: e.g.: Stevens-Johnson Syndrome: SJS** (skin rash, redness of the skin, blistering of the lips, eyes or mouth, skin peeling, accompanied by fever, chills, headache, cough, body aches)			√

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

HOW TO STORE IT

As with all medicines, keep CITALOPRAM out of the reach and sight of children. Store your tablets at room temperature (15°C - 30°C), in a dry place.

Keep the container tightly closed.

There is an expiry date on the label. Do not use the medicine after this date.

If your doctor tells you to stop taking your medicine, you should return any leftover tablets to the pharmacist, unless your doctor tells you to keep them at home.

REMEMBER: This medicine is for YOU. Only a doctor can prescribe it, so never offer it to any other person, even if their symptoms seem to be the same as yours.

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, ON
    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

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