IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

PRESCITALOPRAM
Escitalopram Oxalate Tablets

This leaflet is part III of a three-part "Product Monograph" published when ESCITALOPRAM 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 ESCITALOPRAM as you may want to read it again. This leaflet is a summary and will not tell you everything about ESCITALOPRAM. 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 is the medication used for:
ESCITALOPRAM 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:
ESCITALOPRAM belongs to a group of medicines known as antidepressants, more specifically to the family of medicines called SSRIs (Selective Serotonin Reuptake Inhibitors).

ESCITALOPRAM is thought to work by increasing the levels of a chemical in the brain called serotonin (5-hydroxytryptamine). Disturbances in the serotonin-system are considered an important factor in the development of depression and related diseases.

When it should not be used:
- Do not use ESCITALOPRAM at the same time as pimozide.
- Do not use ESCITALOPRAM if you are currently or have recently taken monoamine oxidase antidepressants (e.g. phenelzine sulphate, moclobemide).
- Do not take ESCITALOPRAM if you are allergic to it, or to any of the components of its formulation (for list of components see the section on "What ESCITALOPRAM contains").
- Stop taking ESCITALOPRAM and contact your doctor immediately if you experience an allergic reaction or any severe side effect.
- Do not use ESCITALOPRAM if you have been diagnosed with a congenital long QT syndrome

What the medicinal ingredient is:
Escitalopram oxalate

What the non medicinal ingredients are:
Croscarmellose sodium, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol and titanium dioxide.

What dosage forms it comes in:
Tablets 10 mg and 20 mg

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.

ESCITALOPRAM 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, or thoughts about suicide, 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 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 ESCITALOPRAM 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 ESCITALOPRAM):
Post-marketing reports indicate that some newborns whose mothers took an SSRI (Selective Serotonin Reuptake Inhibitor) such as escitalopram oxalate 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, bluish skin, seizures, body temperature changes, vomiting, low blood sugar, tense or overly relaxed muscles, vivid reflexes, tremor, jitteriness, irritability, lethargy, sleepiness, sleeping difficulties 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 (PPHN) and newer antidepressants:
When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like ESCITALOPRAM may increase the risk of a serious lung condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), that causes breathing difficulties in newborns soon after birth, making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your doctor immediately.

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 ESCITALOPRAM 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 ESCITALOPRAM, tell your doctor:

- 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 an eating disorder or are following a strict diet
- If you have glaucoma or increased pressure in your eyes
- 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.
- If you are receiving electroconvulsive treatment.
- 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.
- If you ever had an allergic reaction to any medication or any of the ingredients mentioned in this leaflet.
- 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 ESCITALOPRAM 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 ESCITALOPRAM. You should check with your doctor or pharmacist before taking any other medication (prescription, non-prescription or natural/herbal) with ESCITALOPRAM. Other drugs that may interact with ESCITALOPRAM include:

- drugs to treat heart rhythm disturbances (antiarrhythmics)
- antipsychotics
- opioid painkillers
- drugs to treat infections
- Diuretics (water pills)
- Laxatives (including enemas)
- Other SSRIs (citalopram) or any other antidepressant (e.g., imipramine, desipramine)
- Lithium
- Tryptophan
- Cimetidine
- Triptans (e.g., sumatriptan, zolmitriptan, naratriptan)
- Fluconazole
- Ketoconazole
- Itraconazole
- Racemic Citalopram (Celexa)
- 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), acetylsalicylic acid (e.g., Aspirin) and other non-steroidal anti-inflammatory drugs (e.g., 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 ESCITALOPRAM.

Drugs from the class that ESCITALOPRAM 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 ESCITALOPRAM exactly as your doctor has instructed.

Usually your doctor will prescribe 10 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 ESCITALOPRAM you are taking, or that someone in your care is taking unless your doctor tells you to.

- You should continue to take ESCITALOPRAM 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 ESCITALOPRAM 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 ESCITALOPRAM for several months. Continue to follow your doctor's instructions.

Proper Handling Instructions

ESCITALOPRAM Tablets:

- Take everyday, as a single daily dose.
- Swallow the tablets whole with a drink of water. Do not chew them. ESCITALOPRAM tablets can be taken with or without food.

Overdose:

If you have accidentally taken too much ESCITALOPRAM contact your doctor, the Regional Poison Control Centre or nearest hospital emergency department immediately, even if you do not feel sick. If you go to the doctor or the hospital, take the ESCITALOPRAM container with you. Some of the signs of an overdose could be dizziness, tremor, agitation, convulsion, coma, nausea, vomiting, change in heart rhythm, decreased blood pressure and seizure.

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

- ESCITALOPRAM may cause unwanted effects (side-effects). These may include nausea, increased sweating, diarrhoea, fatigue, fever, constipation, clogged or runny nose, sleep disturbance, loss of appetite, increased appetite, increased weight, decreased interest in sex, decreased ability to reach orgasm, erectile dysfunction, anxiety, restlessness, abnormal dreams, difficulties falling asleep, drowsiness, yawning, tremor (shakiness), prickling of the skin, dizziness, dry mouth, heartburn, pain in muscles and joints, stomach pain and changes in heart rate.

- Contact your doctor before stopping or reducing your dosage of escitalopram. 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 escitalopram. 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 escitalopram 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 ESCITALOPRAM, please consult your doctor.

- Usually ESCITALOPRAM 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 ESCITALOPRAM does not affect you adversely.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / effect	**Talk with your doctor or pharmacist right away**		**Seek immediate emergency medical assistance**
	Only if severe	**In all cases**	
Uncommon	**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 alone, hives alone	✓	
	Alteration of blood sugar control in patients with diabetes: Low blood sugar (symptoms of dizziness, lack of energy, drowsiness, headache, trembling, sweating) or High blood sugar (symptoms of increased thirst, increased urination, weakness, confusion, fruity breath odour)	✓	
	Low Platelets: Bruising or unusual bleeding from the skin or other areas	✓	
	Hallucinations: Strange visions or sounds	✓	
	Mania: Overactive behaviour and thoughts	✓	
	Uncontrollable movements of the body or face	✓	
	Inability to urinate	✓	

Rare	**Serotonin syndrome**: a combination of symptoms, possibly including: agitation, confusion, tremor, sudden jerking of muscles, high fever			✓
	Low sodium level in blood : Symptoms of tiredness, weakness, confusion combined with achy, stiff or uncoordinated muscles		✓	
	Glaucoma: Increased pressure in the eye, eye pain, and blurred vision		✓	
Very Rare	**Seizures:** Loss of consciousness with uncontrollable shaking ("fit")			✓
	Liver disorder : symptoms include nausea, vomiting, loss of appetite combined with itching, yellowing of the skin or eyes, dark urine			✓
	Gastrointestinal bleeding : Vomiting blood or passing blood in stools			✓
See Warnings & Precautions	**New or Worsened Emotional or Behavioural Problems**		✓	
	Akathisia: Feeling restless and unable to sit or stand still		✓	
Unknown	**Abnormal heart rate or rhythm, palpitations, fainting**		✓	

This list is not a complete list of side effects. If you have any unexpected effects while taking this drug, contact your doctor or pharmacist.

HOW TO STORE IT

- As with all medicines, keep ESCITALOPRAM out of the reach and sight of children.
- Store your tablets at room temperature (15°-30°C) protected from humidity and 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 the 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

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

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.

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Date of Revision: May 27, 2014