PART III: CONSUMER INFORMATION

Pr BUPROPION SR
Bupropion Hydrochloride
Sustained-Release Tablets 100 mg & 150 mg
Manufacturer's Standard

BUPROPION SR is a **Twice Daily** medication and should not be confused with other bupropion formulations.

This leaflet is part III of a three-part "Product Monograph" published when BUPROPION SR was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about BUPROPION SR. Contact your doctor or pharmacist if you have any questions about the drug.

Please read this information before you start to take your medication, 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:
BUPROPION SR has been prescribed to you 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)

What it does:
BUPROPION SR is one of a group of drugs called antidepressants. BUPROPION SR is thought to block reuptake of chemicals in the brain called *noradrenaline* and *dopamine*, which are linked with depression.

When it should not be used:
Do not take BUPROPION SR if you:

- know that you are allergic to bupropion, the medical ingredient, or any of the other ingredients in BUPROPION SR tablets.
- are taking any other medicines which contain bupropion.
- have been diagnosed with epilepsy or have a history of seizures.
- have or have had an eating disorder**,** for example binge eating (bulimia) or anorexia.
- are usually a heavy drinker who has just stopped or are about to stop drinking
- are taking Monoamine oxidase (MAO) inhibitor antidepressants (e.g. phenelzine sulphate, moclobemide).
- are taking the antipsychotic thioridazine
- have liver or kidney problems
- are pregnant or trying to become pregnant, or if you think that you might be pregnant
- are breast feeding**.**

What the medicinal ingredient is:
Bupropion hydrochloride

What the nonmedicinal ingredients are:
Carnauba wax, hydrochloric acid, hydroxypropyl cellulose, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate, titanium dioxide and water.
100 mg tablets also contain FD&C Blue #1.
150 mg tablets also contain FD&C Blue #2, FD&C Red #40.

What dosage forms it comes in:
100 mg and 150 mg tablets

WARNINGS AND PRECAUTIONS

BUPROPION SR is a **Twice Daily** medication and should not be confused with other bupropion formulations.

During treatment with these types of medication it is important that you and your doctor have good ongoing communication about how you are feeling.

BUPROPION SR 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; for example, they may experience unusual feelings of agitation, hostility or anxiety, or have impulsive or disturbing thoughts such as thoughts of self-harm, or harm to others. Should this happen to you, or to those in your care if you are a caregiver or guardian, consult your doctor immediately. Close observation by a doctor is necessary in this situation**.**

Important Warning About The Risk Of Seizures

- At the maximum recommended dose of 300 mg per day, approximately 1 in every 1000 people taking the maximum dose of BUPROPION SR is at risk of a fit (a seizure or convulsion).

BEFORE you use BUPROPION SR tell your doctor or pharmacist if you:

- have ever had any fits or seizures in the past
- take other medications that may increase your chance of a seizure, including drugs for depression and some antibiotics
- are taking any prescription or over-the-counter medications, or are planning on taking any prescription or over-the-counter medications during your therapy
- have, or have had an eating disorder, for example binge eating (bulimia) or anorexia nervosa
- have liver problems
- have kidney problems
- take more than the recommended amount of BUPROPION SR tablets. BUPROPION SR tablets should NOT be used if you are taking the smoking cessation aid bupropion hydrochloride or any other medications containing bupropion hydrochloride such as bupropion hydrochloride sustained-release tablet.
- have diabetes which is treated with insulin or other medications

- have used over-the-counter diet aids
- have had a serious head injury.
- drink alcohol. It is best not to drink alcohol at all or to drink very little while taking BUPROPION SR. If you drink a lot of alcohol and suddenly stop, you may increase your chance of having a seizure. Be sure to discuss your use of alcohol with your doctor before you begin taking BUPROPION SR.
- are pregnant, or thinking about becoming pregnant, or are breastfeeding.

Driving vehicles or using machinery
BUPROPION SR may impair your ability to perform tasks requiring judgement or motor and cognitive skills. Until you are reasonably certain that BUPROPION SR does not adversely affect your performance you should refrain from driving an automobile or operating hazardous machinery.

Effects on Pregnancy and Newborns
Post-marketing reports indicate that some newborns whose mother took an SSRI (Selective Serotonin Reuptake Inhibitor) or other newer anti-depressant, such as BUPROPION SR, during pregnancy have developed complications at birth requiring prolonged hospitalization, 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 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.

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 with your doctor.

Angle-Closure Glaucoma:
BUPROPION SR can cause an acute attack of glaucoma. Seek immediate medical attention if you experience eye pain, changes in vision, swelling or redness in or around the eye.

INTERACTIONS WITH THIS MEDICATION

If you are taking or have recently been taking other medicines for depression called monoamine oxidase inhibitors (MAOIs) tell your doctor before taking BUPROPION SR.

You should tell your doctor if you are taking or have recently taken any medications (prescription, nonprescription or natural herbal) especially**:**

- other antidepressants such as citalopram, paroxetine, venlafaxine
- the antipsychotic thioridazine
- other medications for mental illness such as haloperidol and risperidone
- medicines for Parkinson's Disease such as levodopa, amantadine or orphenadrine
- medicines used for epilepsy (such as carbamazepine, phenytoin, or phenobarbitone)
- cyclophosphamide or ifosfamide, drugs mainly used to treat cancer
- drugs called beta blockers to treat heart conditions**.**
- medicines to regulate heart rhythm
- medicines used to reduce blood clots (such as ticlopidine or clopidogrel)
- nicotine patches to help you stop smoking
- tamoxifen, a drug to treat breast cancer
- ritonavir or efavirenz, drugs to treat HIV infection
- digoxin, used to treat congestive heart failure and a fast heart rate or irregular heart rhythm such as atrial fibrillation (sometimes called "a-fib")
- In general, drinking alcoholic beverages should be kept to a minimum or avoided completely while taking BUPROPION SR.

PROPER USE OF THIS MEDICATION

Usual dose:
How to take BUPROPION SR

- The usual adult starting dose for sustained release bupropion is one 100 mg or 150 mg tablet once daily. Patients may have a dosage increase after one week to 300 mg daily. In order to minimize the risk of seizures (see WARNINGS) single doses of BUPROPION SR must not exceed 150 mg. Doses of BUPROPION SR greater than 150 mg/day should be administered twice a day preferably with at least 8 hours between successive doses.
- Take your BUPROPION SR tablet at the same time each day. If you have any problems with your dosing routine, contact your doctor or pharmacist.
- Swallow your BUPROPION SR tablet whole, with fluids. Do not divide, chew or crush tablets.
- Take only the recommended dose prescribed by your doctor. Never increase the dose of BUPROPION SR you or those in your care are taking, unless your doctor tells you to.
- The effects of your medication may not be noticeable in the first few days of treatment, and significant improvement may take several weeks. If you are concerned that your medicine is not working, discuss this with your doctor.
- You should 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:
BUPROPION SR should be taken at the same time each day and no more than the recommended dose should be taken each day. If

your normal administration time has been missed, the dose should be skipped and administration resumed at the normal administration time of the following day.

Overdose:
If you take too many tablets, you may increase the risk of a fit or seizure(s), or other serious effects, including irregular heartbeat, which may be life-threatening.

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 medications, BUPROPION SR can cause some side effects. You may not experience any of them. For most patients, these 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 BUPROPION SR are:

- headache
- dry mouth
- nausea
- constipation
- insomnia
- dizziness
- shakiness
- ringing in the ears

Uncommon side effects
These could affect less than one in every 100 people:

- Increased appetite
- Weight increase
- Bloating
- Migraine

New or Worsened Emotional or Behavioural Problems
A small number of patients taking drugs of this type may feel worse instead of better; for example, they may experience new or worsened feelings of agitation, hostility or anxiety, or thoughts about suicide. Your doctor should be informed of such changes immediately. Close observation by a doctor is necessary in this situation. See also the WARNINGS AND PRECAUTIONS section.

Effects on Newborns
Some newborns whose mothers took an SSRI (Selective Serotonin Reuptake Inhibitor) or other newer antidepressant 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

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 call your doctor or pharmacist
		Only if severe	In all cases	
Rare	Seizures [loss of consciousness with uncontrollable shaking ("fit"/" convulsion")]			✓*
Very Rare	Severe allergic reactions [red and lumpy or blistering skin rash, swelling of the face or throat, trouble breathing, collapse, blackout, severe muscle or joint pains]			✓*
Very Rare	Liver disorders, Including hepatitis and Jaundice [symptoms include nausea, vomiting, loss of appetite combined with itching, yellowing of the skin or eyes, dark urine]		✓*	
Very Rare	Poor Blood Glucose control	✓		
Very Rare	Inability to urinate		✓	
Very Rare	Hallucinations, delusions, paranoid ideation [sensing or believing thing that are not there]		✓	
Very Rare	Aggression		✓*	
Very Rare	Low sodium level in blood [tiredness, weakness, confusion combined with achy, stiff or uncoordinated muscles]		✓	

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

See Warnings and Precautions	New or Worsened Emotional or Behavioural Problems		✓*	
See Warnings and Precautions	Rises in Blood Pressure	✓		

*If you think you have these side effects, it is important that you seek medical advice from your doctor straight away.
Approximately 1 in every 1000 people taking the maximum dose of BUPROPION SR is at risk of a fit (a seizure or convulsion). The chance of a seizure happening is higher if you take too much, if you take certain medicines at the same time, if you drink alcohol, or if you are at higher than usual risk of seizures.

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

HOW TO STORE IT

- Keep all medication out of the reach of children.
- Store BUPROPION SR between 15°C and 25°C.
- Keep container tightly closed.
- Store in a dry place.
- Protect from light.
- If your doctor tells you to stop taking BUPROPION SR 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 found 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: August 11, 2017