PART III: CONSUMER INFORMATION

Pr STRATTERA®
(atomoxetine capsules)

This leaflet is part III of a three-part "Product Monograph" published when STRATTERA was approved for sale in Canada and is designed specifically for adults and parents of children/adolescents who will be prescribed this medication. This leaflet is a summary and will not tell you everything about STRATTERA. Contact your doctor or pharmacist if you have any questions about this drug.

ABOUT THIS MEDICATION

What STRATTERA is used for:

STRATTERA is a medicine for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children 6 years of age and over, adolescents, and adults. STRATTERA should not be used in children under 6 years of age.

STRATTERA is a part of your overall treatment program for ADHD that may include other measures (psychological, educational, and social). Your doctor may also recommend other therapy.

What it does:

STRATTERA is a selective norepinephrine reuptake inhibitor medicine that increases the amount of noradrenaline, a natural chemical in the brain. STRATTERA may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

STRATTERA works differently from other medicines used for the treatment of ADHD. STRATTERA is not a stimulant and is not addictive.

What is ADHD:

ADHD has 3 main types of symptoms: inattention, hyperactivity, and impulsiveness. Symptoms of inattention include not paying attention, making careless mistakes, not listening, not finishing tasks, not following directions, and being easily distracted. Symptoms of hyperactivity and impulsiveness include fidgeting, talking excessively, running around at inappropriate times, and interrupting others. Some patients have more symptoms of hyperactivity and impulsiveness while others have more symptoms of inattentiveness. Some patients have all 3 types of symptoms.

Symptoms of ADHD in adults may include a lack of organization, problems starting tasks, impulsive actions, daydreaming, daytime drowsiness, slow processing of information, difficulty learning new things, irritability, lack of motivation, sensitivity to criticism, forgetfulness, low self-esteem, and excessive effort to maintain some organization. The symptoms shown by adults who primarily have attention problems but not hyperactivity have been commonly described as Attention-Deficit Disorder (ADD).

Many people have these symptoms from time to time. However, people with ADHD have these symptoms most of the time. Symptoms must be present for at least 6 months to be certain of the diagnosis. In addition, the symptoms cause problems in more than one area of life (home, school, work, or social situations).

When it should not be used:

Do not take STRATTERA if you:

- are taking, or have recently taken, an antidepressant medicine known as a monoamine oxidase inhibitor (MAOI). Some names of MAOI medicines are phenelzine and tranylcypromine.
- have narrow angle glaucoma, an eye disease.
- are allergic to atomoxetine or any other ingredient of STRATTERA.
- have symptomatic cardiovascular disease.
- have moderate to severe high blood pressure.
- have advanced arteriosclerosis (hardened arteries).
- have uncontrolled hyperthyroidism (an overactive thyroid gland).
- have a tumour of the adrenal gland (phaeochromocytoma).

What the medicinal ingredient is:

Atomoxetine

What the nonmedicinal ingredients are:

The capsules contain pregelatinized starch and dimethicone. The capsule shells contain gelatin, sodium lauryl sulfate, and one or more of the following: FD&C Blue No. 2, synthetic yellow iron oxide, titanium dioxide.

What dosage forms it comes in:

Capsules of STRATTERA contain 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, or 100 mg of atomoxetine.

WARNINGS AND PRECAUTIONS

The following have been reported with use of STRATTERA and also with stimulant medications:

1. **Suicidal thoughts and actions in children and teenagers**

Some children and teenagers may have a higher chance of having suicidal thoughts or actions. Tell your child or teenager's doctor if your child or teenager (or there is a family history of):

- has bipolar illness (manic-depressive illness)
- had suicidal thoughts or actions before starting STRATTERA.

The chance for suicidal thoughts and actions are higher:
- early during STRATTERA treatment
- during dose adjustments.

Prevent suicidal thoughts and action in your child or teenager by:
- paying close attention to your child or teenager's moods, behaviours, thoughts, and feelings during STRATTERA treatment
- keeping all follow-up visits with your child or teenager's doctor as scheduled.

Watch for the following signs in your child or teenager during STRATTERA treatment:
- anxiety
- agitation
- panic attacks
- trouble sleeping
- irritability
- hostility
- aggressiveness
- impulsivity
- restlessness
- mania
- depression
- suicidal thoughts.

Call your child or teenager's doctor right away if they have any of the above signs, especially if they are new, sudden, or severe. Your child or teenager may need to be closely watched for suicidal thoughts and actions or need a change in medicine.

Should any of the above signs also happen to you while taking STRATTERA, it is important that you talk to your doctor about how you are feeling.

2. Severe liver damage

Call your doctor right away if you or your child have the following signs of liver problems:
- itching
- right upper belly pain
- dark urine
- yellow skin or eyes
- unexplained flu-like symptoms

3. Heart-related problems:

- **sudden death in patients who have heart problems or heart defects as well as in patients without pre-existing cardiac disease.**
- **stroke and heart attack in adults**
- **increased blood pressure and heart rate**

Tell your doctor if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems. Your doctor may wish to check you or your child carefully for heart problems before starting STRATTERA.

Your doctor may wish to check you or your child's blood pressure and heart rate regularly during treatment with STRATTERA.

Call your doctor right away if you or your child has any signs of heart problems such as chest pain, irregular heart rate, palpitations, shortness of breath, dizziness or fainting while taking STRATTERA.

4. New mental (psychiatric) problems in children and teenagers:

- new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms.

Call your child or teenager's doctor right away about any new mental symptoms. STRATTERA treatment may be stopped.

BEFORE you use STRATTERA, talk to your doctor or pharmacist if you or your child:

- have or had suicidal thoughts or actions
- have structural heart abnormalities,
- inborn, acquired or family history of long QT interval
- have mental problems, including psychosis, mania, bipolar illness, or depression;
- have had seizures (convulsions, epilepsy) or abnormal EEGs (electroencephalograms);
- have or had any disorder of the blood vessels in the brain (e.g. aneurysm, stroke, vasculitis);
- have a family history of sudden death or death related to heart problems;
- do strenuous exercise;
- take other drugs for ADHD;
- have or had liver problems. You may need a lower dose;
- have mild high blood pressure. STRATTERA can increase blood pressure;
- have problems with your heart or an irregular heartbeat. STRATTERA can increase heart rate (pulse);
- have low blood pressure. STRATTERA can cause dizziness or fainting in people with low blood pressure
- are nursing, pregnant, or thinking of becoming pregnant;
- have circulation problems in fingers and toes, including numbness; feeling cold or pain (Raynaud's Phenomenon).

Do not drive a car or operate hazardous machinery until you know how STRATTERA affects you.

This medicine was prescribed for your use only. Do not let anyone else take your STRATTERA.

INTERACTIONS WITH STRATTERA

Tell your doctor about all the medicines you/your child take or plan to take, including prescription and non-prescription medicines, dietary supplements, and herbal remedies. Your doctor will decide if you can take STRATTERA with your other medicines. Also tell your doctor if there have been any changes in dosing with your other medicines.

Certain medicines may change the way your body reacts to STRATTERA.

Drugs that may interact with STRATTERA include:

- Anti-depression medicines: Your doctor may need to change your dose of STRATTERA if you are taking paroxetine, fluoxetine, or certain other medicines like quinidine.

  You should not take STRATTERA if you are taking desipramine.

- Asthma medicines: STRATTERA may change the way your body reacts to oral, intravenous, or nebulized salbutamol (or drugs with similar actions), but the effectiveness of these drugs will not be changed.

- Blood pressure medicines: STRATTERA should be used with caution if you are being treated with drugs for high blood pressure.

PROPER USE OF STRATTERA

Usual dose:

Take STRATTERA exactly as directed by your doctor. It is very important that you do not take a larger dose of STRATTERA than prescribed by your doctor.

Your doctor may tell you to take STRATTERA once a day or twice a day (morning and late afternoon/early evening). To help you remember to take STRATTERA, you may want to take it at the same time every day.

Improvement of your ADHD symptoms is generally observed within 1 to 4 weeks of starting STRATTERA.

STRATTERA may be taken with or without food.

You should not open STRATTERA capsules, but if they are accidentally opened or broken, avoid contact with the powder and wash away any loose powder as soon as possible with water. If any of the powder gets in your eyes you should rinse them with water immediately and contact your doctor.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, take it as soon as possible, but do not take more than your total daily dose in any 24-hour period.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

All prescription medicines may cause side effects in some patients. If you have some side-effects such as upset stomach, nausea, sleepiness or tiredness, your doctor may ask you to take STRATTERA twice a day with meals, or in the evening. Most side effects will disappear after the first few weeks.

The following common side effects were reported in clinical trials with STRATTERA:

In teenagers and children over 6:
- upset stomach
- decreased appetite
- nausea or vomiting
- dizziness
- tiredness
- constipation
- low blood pressure
- weight loss may occur especially in the first few weeks.

In Adults:
- constipation
- dry mouth
- nausea
- decreased appetite
- dizziness
- problems sleeping
- sexual side effects
- problems urinating
- menstrual cramps
- rapid or irregular heartbeat
- tiredness

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM				
Symptom / effect		**Talk with your doctor or pharmacist**		**Stop taking drug and seek immediate emergency help**
		Only if severe	**In all cases**	
Very common	**Heart-related problems**: Blood pressure increased, heart rate increased**.** (see **Warnings and Precautions**)		✓	
Common Rare (in children)	**Urinary retention:** problem passing urine and emptying bladder		✓	
Uncommon	**Allergic Reaction:** Swelling, hives, or difficulty breathing			✓
	Suicidal Behavior: Thoughts or actions about hurting or killing yourself. (see **Warnings and Precautions**)			✓
	New psychotic symptoms: Paranoia, delusions-hallucinations (seeing, feeling or hearing things that are not real)		✓	
	Aggressive Behavior or Hostility		✓	
Rare	**Liver Injury:** Dark urine, yellow skin/ eyes, upper right-sided abdominal tenderness, or flu-like symptoms		✓	
	Priapism: Long-lasting (greater than 4 hours in duration) and painful erection of the penis			✓
	Raynaud's Phenomenon: discoloration of the fingers and toes, pain, sensations of cold and/or numbness		✓	
Unknown	**Slowing of growth in children** (height and weight)		✓	
	New manic symptoms: Mania (feeling unusually excited, overactive, or un-inhibited)		✓	

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

HOW TO STORE IT

STRATTERA should be stored at room temperature (15 to 30°C).

Keep all medicines, including STRATTERA, out of the reach of children.

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

For more information, please contact your healthcare professionals or pharmacist first, or Eli Lilly Canada Inc. at: 1-888-545-5972 or visit the website at *www.lilly.ca.*

The information in this document is current as of the last revision date shown below. For the most current information please visit our website or contact us directly.

STRATTERA is a trademark owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates.

This leaflet was prepared by Eli Lilly Canada Inc., Toronto, Ontario, M1N 2E8.

Last revised: October 1, 2015