

PART III: CONSUMER INFORMATION

PrSERTRALINE

(Sertraline Hydrochloride Capsules)

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

Please read this information carefully before you start to take your medicine, even if you have taken this drug before.

ABOUT THIS MEDICATION

What the medication is used for:

SERTRALINE has been prescribed to you by your doctor to relieve your symptoms of the following conditions:

- Depression (feeling sad, a change in appetite or weight, difficulty concentrating or sleeping, feeling tired, headaches, unexplained aches and pain)
- Obsessive-compulsive disorder
- Panic disorder (repeated, unexpected panic attacks)

What it does:

SERTRALINE (sertraline hydrochloride) belongs to a group of medicines known as antidepressants, more specifically to the family of medicines called SSRIs (**S**elective **S**erotonin **R**euptake **I**nhibitors).

SERTRALINE 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 SERTRALINE if you are allergic to it or to any of the components of its formulation (see list of components at the end of this section). Stop taking the drug and contact your doctor immediately if you experience an allergic reaction or any severe or unusual side effect.
- § Do not use SERTRALINE if you are currently taking or have recently taken monoamine oxidase inhibitors, antidepressants (e.g. phenelzine sulphate, tranylcypromine sulphate, moclobemide)
 - Do not use SERTRALINE at the same time as pimozide.

What the medicinal ingredient is:

Sertraline hydrochloride

What the nonmedicinal ingredients are:

Nonmedicinal ingredients include: lactose monohydrate; magnesium stearate; pregelatinized starch; sodium lauryl sulfate.

Capsule shells contain colloidal silicon dioxide, gelatin, sodium lauryl sulfate, titanium dioxide and dye D&C Yellow #10. Capsules 25 mg and 50 mg also contain dye FD&C Yellow #6 and capsules 100 mg also contain dye FD&C Red #40. The capsules do not contain tartrazine or gluten.

What dosage forms it comes in:

SERTRALINE is available as 25 mg (yellow capsule), 50 mg (white and yellow capsule) and 100 mg (orange capsule).

WARNINGS AND PRECAUTIONS

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

SERTRALINE is not for use in children under 18 years of age.

Changes in Feelings and Behaviour:

It is important that you have good communication with your doctor about how you feel. Discussing your feelings and treatment with a friend or relative who can tell you if they think you are getting worse is also useful.

Some patients may feel worse when first starting or changing the dose of drugs such as SERTRALINE. You may feel more anxious or may have thoughts of hurting yourself or others, especially if you have had thoughts of hurting yourself before. These changes in feelings can happen in patients treated with drugs like SERTRALINE for any condition, and at any age, although it may be more likely if you are aged 18 to 24 years old. **If this happens, see your doctor immediately.** Do not stop taking SERTRALINE on your own.

Taking SERTRALINE 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 taking SERTRALINE tell your doctor or pharmacist:

- all your medical conditions
- including a history of:
 - seizures
 - liver disease
 - kidney disease
 - high cholesterol
 - heart disease

- heart rhythm problems
- slow heart beat
- are taking medications for your heart
- manic episodes
- if in your family there is a history of :
 - people younger than 50 years of age having a heart attack
- if the levels of electrolytes in your body are either too high or too low or you have a condition (such as an eating disorder) that can affect your electrolyte levels
- if you have had a stroke
- if you are known to have heart problems (or predispositions) related to a genetic expression (or modification, variant)
- if you have had a head injury
- if you have diabetes
- if you have a bleeding disorder or have been told that you have low platelets;
- if you have blood pressure problems;
- any medications (prescription or non-prescription) which you are taking or have recently taken (within last 14 days), especially monoamine oxidase (MAO) inhibitors (e.g. phenelzine sulfate, tranylcypromine sulfate, moclobemide) or any other antidepressants, pimozide (an antipsychotic drug), drugs used to treat diabetes, drugs used to thin the blood (anticoagulant), the antibiotic linezolid, methylthioninium chloride (methylene blue) or drugs that affect serotonin (including but not limited to fentanyl, fenfluramine and tryptophan);
- If you are pregnant or thinking about becoming pregnant, or if you are breast-feeding;
- if you have a recent bone fracture or were told you have osteoporosis or risk factors for osteoporosis;
- 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;
- if you have ever had any allergic reaction to medications, food, etc.

Effects on Pregnancy and Newborns

If you are already taking SERTRALINE 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.

Some newborns whose mothers took an SSRI (selective serotonin reuptake inhibitor) or other newer antidepressants, such as sertraline hydrochloride, 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 SSRI or other 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 SERTRALINE 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.

Angle-closure Glaucoma

Sertraline hydrochloride can cause an acute attack of glaucoma. Having your eyes examined before you take SERTRALINE 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

INTERACTIONS WITH THIS MEDICATION

Do not use SERTRALINE if you are taking or have recently taken monoamine oxidase inhibitors.

You should avoid taking St. John's Wort if you are taking SERTRALINE.

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

- other antidepressants, such as SSRIs and certain tricyclics;
- other drugs that affect serotonin such as, amphetamines, lithium, linezolid, tramadol, tryptophan, 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;
- certain medicines used to treat schizophrenia;
- certain medicines used to treat bipolar depression, such as lithium;
- metoprolol or other medications used to treat high blood pressure and angina;
- certain medicines which may affect blood clotting and increase bleeding, such as oral anti-coagulants (e.g. warfarin, dabigatran), acetylsalicylic acid (e.g. Aspirin) and other non-steroidal anti-inflammatory drugs (e.g. ibuprofen);
- certain medicines used to treat epilepsy;
- cimetidine;
- in general, drinking alcoholic beverages should be kept to a minimum or avoided completely while taking SERTRALINE.

PROPER USE OF THIS MEDICATION

Usual Dose:

- It is very important that you take SERTRALINE exactly as your doctor has instructed.
- Never increase or decrease the amount of SERTRALINE you or those in your care, if you are a caregiver or guardian, are taking unless your doctor tells you to.
- Do not stop taking this medication without consulting your doctor.
- As with all antidepressants, improvement with SERTRALINE is gradual. You should continue to take SERTRALINE even if you do not feel better, as it may take several weeks for your medication to work. Improvement may be gradual.
- SERTRALINE should be taken with food either in the morning or the evening. You should swallow the capsule whole; do not divide, crush or chew the capsules.

REMEMBER: This medicine has been prescribed only for you. Do not give it to anybody else. If you have any further questions, please ask your doctor or pharmacist.

Overdose:

In case of overdose, contact your doctor, the regional Poison Control Centre, or the nearest hospital emergency department, even though you may not feel sick. Take your medicine with you.

Missed Dose:

If you happen to miss a dose, do not take the missed dose. Just take your next dose at the right time. Do not take a double dose

to make up for a forgotten dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medications, SERTRALINE 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.

If you experience an allergic reaction (including 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) or any severe or unusual side effects, stop taking the drug and contact your doctor immediately.

Some side effects of SERTRALINE are:

- headache
- nausea
- dry mouth
- diarrhea
- loss of appetite
- sleepiness
- dizziness
- insomnia
- sexual problems including decreased libido, erectile dysfunction and ejaculation failure
- nervousness
- tremor

SERTRALINE 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.

Cases of loss of blood sugar level control including both higher and lower-than normal sugar level have been reported in patients receiving SSRIs including SERTRALINE, with and without pre-existing diabetes. Symptoms associated with low blood sugar level in your blood include weakness, hunger, anxiety, sweating, numbness or tingling in your extremities. These are early warning symptoms and should not be ignored. Contact your doctor if you experience these symptoms.

SERTRALINE may raise cholesterol levels in some patients. Blood cholesterol tests may be required by your doctor during treatment with SERTRALINE.

Discontinuation Symptoms

Contact your doctor before stopping or reducing your dosage of SERTRALINE. Symptoms such as dizziness, abnormal dreams, electric shock sensations, agitation, anxiety, difficulty concentrating, headache, tremor, nausea, vomiting, sweating or other symptoms may occur after stopping or reducing the

dosage of SERTRALINE. 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 SERTRALINE to alleviate the symptoms.

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 attention
		Only if severe	In all cases	
Uncommon	Akathisia: feeling restless and unable to sit or stand still		✓	
	Allergic reactions: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
	Bruising or unusual bleeding from the skin or other areas Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
	Low blood sugar: symptoms of dizziness, lack of energy, drowsiness		✓	
	Low sodium level in blood: symptoms of tiredness, weakness, confusion combined with achy, stiff or uncoordinated muscles Mania/hypomania: elevated or irritable mood, decreased need for sleep, racing thoughts		✓	

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 attention
		Only if severe	In all cases	
	Uncontrollable movements of the body or face Heart Rhythm problems: dizziness, increased heart rate, fainting or seizures		✓	✓
Rare	Gastrointestinal bleeding: vomiting blood or passing blood in stools Glaucoma: swelling or redness in or around the eye, eye pain and changes in vision Seizures: (loss of consciousness with uncontrollable shaking “fit”)		✓	✓ ✓
Unknown	Low Platelets: Bruising or unusual bleeding from the skin or other areas.		✓	
See Warnings and Precautions	Serotonin syndrome: a combination of most or all of the following; confusion, restlessness, sweating, shaking, shivering, sudden jerking of the muscles, hallucinations, fast heartbeat Changes in feelings or behaviour (anger, anxiety, suicidal or violent thoughts)		✓	✓

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

HOW TO STORE IT

Store at room temperature (15 to 30°C) in a dry place.
Keep the container tightly closed.
Keep out of reach of children.

If your doctor decides to stop SERTRALINE treatment, return any leftover medicine to your pharmacist to safely dispose of it. Keep it only if your doctor tells you to do so.

Reminder: This medicine has been prescribed only for you. Do not give it to anybody else. If you have any further questions, please ask your doctor or pharmacist.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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:

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