

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr**ZOLOFT**<sup>®</sup>

#### Sertraline Hydrochloride Capsules

Read this carefully before you start taking **ZOLOFT** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ZOLOFT**.

#### Serious Warnings and Precautions

##### New and worsened emotional or behaviour problems:

- When you first start taking **ZOLOFT** or when your dose is adjusted, you may feel worse instead of better. You may feel new or worsened feelings of agitation, hostility, anxiety or impulsivity.
- During your treatment with **ZOLOFT**, it is important that you and your healthcare professional talk regularly about how you are feeling. They will closely monitor you for signs of new or worsened emotions or behaviours while you are taking **ZOLOFT**.
- You may find it helpful to tell a relative or close friend that you are depressed. Ask them to read this leaflet. You might ask them to tell you if they:
  - think your depression is getting worse, or
  - are worried about changes in your behaviour.
- If your depression worsens or you experience changes in your behaviour, tell your healthcare professional right away. Do not stop taking your medicine as it takes time for **ZOLOFT** to work.

##### Self-harm or suicide:

- Antidepressants, such as **ZOLOFT**, can increase the risk of suicidal thoughts and actions.
- If you have thoughts of harming or killing yourself at any time, tell your healthcare professional or go to a hospital right away. Close observation by a healthcare professional is necessary in this situation.

#### What is **ZOLOFT** used for?

**ZOLOFT** is used in **adults** 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)
- **Obsessive-compulsive disorder** (recurrent and intrusive thoughts, feelings, ideas, or sensations; recurrent pattern of behaviour, or unwanted thoughts or actions)
- **Panic disorder** (repeated, unexpected panic attacks)

### **How does ZOLOFT work?**

ZOLOFT 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).

ZOLOFT is thought to work by increasing the levels of a chemical in the brain called serotonin. This helps to relieve your symptoms of depression, obsessive-compulsive disorder and/or panic disorder.

### **What are the ingredients in ZOLOFT?**

Medicinal ingredients: Sertraline Hydrochloride

Non-medicinal ingredients: Cornstarch; lactose (anhydrous); magnesium stearate; sodium lauryl sulfate. Capsule shells contain gelatin, titanium dioxide and dye D & C Yellow #10. The 25 mg and 50 mg capsules also contain dye FD & C Yellow #6 and the 100 mg capsules also contain dye FD& C #40.

### **ZOLOFT comes in the following dosage forms:**

Capsules: 25 mg, 50 mg and 100 mg sertraline (as sertraline hydrochloride).

### **Do not use ZOLOFT if:**

- you are allergic to sertraline hydrochloride or to any of the non-medicinal ingredients in ZOLOFT (see **What are the ingredients in ZOLOFT**).
- you are currently taking or have recently taken any monoamine oxidase inhibitors (MAOIs), such as phenelzine sulphate, tranylcypromine sulphate, moclobemide. If you are unsure, ask your healthcare professional.
- you are currently taking pimozone

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ZOLOFT. Talk about any health conditions or problems you may have, including if you:**

- have any diseases or conditions that affect your metabolism or heart function
- have or have a history of:
  - seizures
  - liver disease
  - high cholesterol
  - heart disease
  - heart rhythm problems
  - slow heart beat
  - taking medications for your heart
  - manic episodes
- have a family history of people younger than 50 years of age having a heart attack

- have 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
- have had a stroke
- are known to have heart problems or have been told you are at risk for heart problems
- have diabetes
- have or have a history of a bleeding disorder or have been told that you have low platelets
- have blood pressure problems;
- are pregnant or thinking about becoming pregnant, or if you are breast feeding
- had a recent bone fracture or were told you have osteoporosis or risk factors for osteoporosis
- drink alcohol and/or use street drugs
- have ever had any allergic reaction to medications, food, etc.

**Other warnings you should know about:**

**Do NOT stop taking ZOLOFT without talking to your healthcare professional first, as it may cause unwanted side effects such as headache, insomnia, numbness, tingling, burning, or prickling, nervousness, anxiety, nausea, sweating, dizziness, jitteriness and weakness.**

**Pregnancy:** Only take ZOLOFT during pregnancy if you and your healthcare professional have discussed the risks and have decided that you should. If you take ZOLOFT near the end of your pregnancy, you may be at a higher risk of heavy vaginal bleeding shortly after birth. If you become pregnant while taking ZOLOFT, tell your healthcare professional right away.

**Effects on newborns:** In some cases, babies born to a mother taking ZOLOFT during pregnancy may require hospitalization, breathing support and tube feeding. Be ready to seek medical help for your newborn if they:

- have trouble breathing or feeding,
- have muscle stiffness, or floppy muscles (like a rag doll)
- have seizures (fits)
- are shaking (jitteriness)
- are constantly crying

If you take ZOLOFT:

- During early pregnancy, there is a possible slight increased risk that your newborn may have a heart defect.
- During late pregnancy, your newborn may be at risk of having a serious lung condition called Persistent Pulmonary Hypertension of the Newborn (PPHN), which causes breathing problems.

**Falls and fractures:** ZOLOFT can cause you to feel sleepy or dizzy and can affect your balance. This increases your risk of falling, which can cause fractures or other fall related-injuries, especially if you:

- take sedatives
- consume alcohol
- are elderly
- have a condition that causes weakness or frailty

**Serotonin toxicity (also known as Serotonin Syndrome):** ZOLOFT can cause serotonin toxicity, a rare but potentially life-threatening condition. It can cause serious changes in how your brain, muscles and digestive system work. You may develop serotonin toxicity if you take ZOLOFT with certain anti-depressants or migraine medications. Serotonin toxicity symptoms include:

- fever, sweating, shivering, diarrhea, nausea, vomiting;
- muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination
- fast heartbeat, changes in blood pressure;
- confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma

**Driving and using machines:** ZOLOFT may make you feel sleepy. Give yourself time after taking ZOLOFT to see how you feel before driving a vehicle or using machinery.

**ZOLOFT can cause serious side effects including:**

- Angle-closure glaucoma (sudden eye pain or change in vision)
- Heart rhythm problems
- Sexual dysfunction

See the **Serious side effects and what to do about them** table below for more information on these and other serious side effects.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

#### **Serious Drug Interactions**

**Do not take ZOLOFT if you:**

- are taking or have recently taken (in the last 14 days) any MAOIs such as phenelzine, tranylcypromine, linezolid, methylene blue as you may have serious side effects
- are taking pimozide, an antipsychotic medicine (used to manage psychosis)

### The following may also interact with ZOLOFT:

- other antidepressants, such as SSRIs and certain tricyclics
- other drugs that affect serotonin such as, amphetamines, opioids, tryptophan, fenfluramine
- certain medicines called “triptans” which are used to treat migraines, such as almotriptan, sumatriptan, rizatriptan, naratriptan, zolmitriptan
- certain medicines used to treat pain, such as fentanyl (used in anaesthesia or to treat chronic pain), tramadol, tapentadol, meperidine, methadone, pentazocine
- metamizole, used to treat fever or pain
- certain medicines used to treat cough, such as dextromethorphan
- certain medicines used to treat bipolar depression, such as lithium
- drugs that affect your electrolyte levels such as diuretics (“water pills”), laxatives and enemas, amphotericin B, high dose corticosteroids (drugs that reduce inflammation)
- drugs that can affect how your blood clots such as warfarin, dabigatran, acetylsalicylic acid (Aspirin) and other non-steroidal anti-inflammatory drugs (NSAIDs)
- certain medicines used to treat seizures such as phenytoin
- cimetidine, a medicine used to treat heartburn
- insulin or oral medicines used to treat diabetes
- an herbal medicine called St. John’s Wort
- alcohol, it is recommended to avoid drinking alcohol while taking ZOLOFT

### How to take ZOLOFT:

- It is very important that you take ZOLOFT exactly as your healthcare professional has instructed
- Keep taking ZOLOFT unless your healthcare professional tells you to stop.
- Continue to take ZOLOFT even if you do not feel better, as it may take several weeks for your medicine to start working.
- Take with food either in the morning or the evening.
- Swallow the capsules whole, do not divide, crush or chew them.

**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.**

### Usual dose:

**Depression:** The usual starting dose is 50 mg once daily. Your healthcare professional may decide to slowly increase your dose. The maximum dose is 200 mg daily.

**Obsessive-compulsive disorder:** The usual starting dose is 50 mg once daily. Your healthcare professional may decide to slowly increase your dose. The maximum dose is 200 mg daily.

**Panic disorder:** The usual starting dose is 25 mg once daily. Your healthcare professional may decide to slowly increase your dose. The maximum dose is 200 mg daily.

**Overdose:**

If you think you, or a person you are caring for, have taken too much ZOLOFT, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you 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 missed dose.

**What are possible side effects from using ZOLOFT?**

These are not all the possible side effects you may have when taking ZOLOFT. If you experience any side effects not listed here, tell your healthcare professional.

- headache
- nausea
- dry mouth
- diarrhea
- loss of appetite
- indigestion
- sleepiness
- dizziness
- insomnia
- nervousness
- agitation
- tremor
- increased sweating

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>COMMON</b>			
<b>Sexual dysfunction:</b> low sex drive, not being able to ejaculate, delayed ejaculation, erectile dysfunction		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNCOMMON</b>			
<b>Akathisia</b> (a type of movement disorder): feeling restless and unable to sit or stand still		✓	
<b>Allergic reactions:</b> rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, wheezing, feeling sick to your stomach and throwing up			✓
<b>Bruising</b> or unusual bleeding from the skin or other areas		✓	
<b>Heart rhythm problems:</b> dizziness, increased heart rate, fainting or seizures			✓
<b>Liver Disorder:</b> yellowing of the skin or eyes, dark urine and pale stools, abdominal pain, nausea, vomiting, loss of appetite		✓	
<b>Low blood sugar:</b> dizziness, lack of energy, drowsiness		✓	
<b>Low sodium level in the blood:</b> tiredness, weakness, confusion combined with achy, stiff or uncoordinated muscles		✓	
<b>Mania:</b> elevated or irritable mood, decreased need for sleep, racing thoughts		✓	
<b>Uncontrollable movements</b> of the body or face		✓	
<b>RARE</b>			
<b>Angle-closure glaucoma</b> (sudden eye pain): increased pressure in your eyes, eye and head pain, swelling or redness in or around the eye, hazy or blurred vision, sudden loss of sight			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Eosinophilic pneumonia</b> fatigue, muscle pain, lung chest pain, shortness of breath, respiratory symptoms		✓	
<b>Gastrointestinal bleeding</b> (bleeding in the stomach or bowels): vomiting blood, black/tarry stool, blood in the stool		✓	
<b>Seizures (fits):</b> uncontrollable shaking with or without loss of consciousness			✓
<b>Serotonin toxicity:</b> a reaction which may cause feelings of agitation or restlessness, flushing, muscle twitching, involuntary eye movements, heavy sweating, high body temperature (> 38°C), or rigid muscles			✓
<b>UNKNOWN</b>			
<b>Changes in feelings or behavior</b> (anger, anxiety, suicidal or violent thoughts)		✓	
<b>Thrombocytopenia</b> (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue, weakness		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.



### **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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) 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.*

### **Storage:**

- Store ZOLOFT at room temperature (15-30°C).
- Keep container tightly closed.
- If your healthcare professional tells you to stop taking ZOLOFT please return any leftover medicine to your pharmacist.

Keep out of reach and sight of children.

### **If you want more information about ZOLOFT:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the website [www.viatris.ca](http://www.viatris.ca), or by calling 1-844-596-9526.

This leaflet was prepared by BGP Pharma ULC.

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BGP Pharma ULC  
Etobicoke, Ontario, M8Z 2S6

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