

APO-SERTRALINE CAPSULES

Sertraline hydrochloride (50mg)

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What Apo-Sertraline is used for

Apo-Sertraline has been prescribed to you by your doctor to relieve your symptoms of the following conditions:

- depression
- panic disorder, with or without agoraphobia (fear of public or open spaces)
- obsessive-compulsive disorder (OCD) (persistent, obsessive thoughts that make you carry out repetitive behaviour)

How Apo-Sertraline works

Apo-Sertraline contains the active ingredient sertraline and belongs to a family of medicines called Selective Serotonin Reuptake Inhibitors (SSRI).

Apo-Sertraline is believed to work by enhancing the availability of serotonin, one of the chemical substances in the brain. Depression and OCD have been associated with a decrease in the flow of serotonin between certain brain cells.

Before you use Apo-Sertraline

- When you must not use it

Do not use Apo-Sertraline if you are allergic to Sertraline Hydrochloride, or any other ingredients in this medication. (see Product Description).

Do not take Apo-Sertraline if you are taking pimozone (a medicine used for mental disorder or nervous system disorder)

Monoamine oxidase inhibitor (MAOI)

Do not take Apo-Sertraline until 14 days after stopping any MAOI, and do not take MAOIs until 14 days after stopping Apo-Sertraline. Your doctor will know when it is safe to start Apo-Sertraline after the MAOI has been stopped.

Cases of serious reactions, sometimes fatal, have been reported in people receiving sertraline in combination with a MAOI, including selegiline (used for Parkinson's disease) and moclobemide (used for depression). Some cases presented with features resembling serotonin syndrome. (see section **Side effects**)

Check with your doctor or pharmacist if you are unsure as to whether or not you had taken or are taking a MAOI.

- Before you start to use it

Before taking Apo-Sertraline your doctor needs to know any other medical condition that you may have including:

- a history of seizures (fits)
- a history of mania (feeling elated or over-excited, which causes unusual behaviour) or hypomania (a condition similar to mania but less severe)
- liver problems
- kidney problems

Pregnancy and breastfeeding

The safety of sertraline during pregnancy and lactation has not been established. Do not take Apo-Sertraline if you are pregnant, breast-feeding, trying to get pregnant or think you may be pregnant unless the potential benefits to the patient outweigh the possible hazards to the fetus. Ask your doctor or pharmacist for advice before taking any medicine.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food

shop.

Some medicines may interfere with Apo-Sertraline. These include:

- MAOIs (see When you must not use it)
- pimozone (see When you must not use it)
- seizure medications (e.g. carbamazepine, phenytoin)
- tryptophan, an amino acid
- St. John Wort, a herbal remedy used for depression
- Medicines used to treat mental illness (e.g. lithium)
- Tramadol (For moderate to severe pain),
- Sumatriptan (For migraine headache)
- Fenfluramine (For obesity)
- alcohol
- cimetidine (For heartburn, stomach ulcers)
- warfarin (For stopping blood from clotting)

How to use Apo-Sertraline

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Depression and Obsessive-Compulsive Disorder: A dose of 50 mg/day is recommended as the initial dose.

Panic disorder: Apo-Sertraline treatment should be initiated with a dose of 25 mg once daily.

Titration: In depression, OCD and panic disorder, a gradual increase in dosage may be considered if no clinical improvement is observed. Doses should not exceed a maximum of 200 mg/day.

The full therapeutic response may be delayed until 4 weeks of treatment or longer.

<p><i>Maintenance:</i> During long-term therapy for any indication, the dosage should be maintained at the lowest effective dose and you should be periodically reassessed to determine the need for continued treatment.</p>	<p>anxiety and dilated pupils.</p>	<p>you want to discuss this, please go back to your doctor. Families or caregivers should pay close attention to your child whenever Apo-Sertraline is started or its dose is changed.</p>
<p>If you are having liver problems, your doctor may decide that you should have a lower dose of Apo-Sertraline.</p>	<p>While you are using it</p>	<p>Contact your doctor if you notice any sudden or unusual changes in you or your child's behaviour.</p>
<p>Apo-Sertraline should not be used in the treatment of children and adolescents under the age of 18 years with major depressive disorder.</p>	<p>- <u>Things you must do</u></p>	<p>Side effects Like all medicines, Apo-Sertraline can cause side effects, although not everybody gets them.</p>
<p>- <u>When to use it</u> Use as directed by your doctor or pharmacist.</p>	<p>Take your medicine exactly as your doctor has told you. Tell all the doctors, dentists and pharmacists treating you that you are taking Apo-Sertraline.</p>	<p>If you experience the following very serious side effect, stop taking Apo-Sertraline and tell your doctor immediately or contact the casualty department at your nearest hospital:</p>
<p>Apo-Sertraline should be taken with food once daily, preferably with the evening meal. If you prefer to take it in the morning, take it with breakfast.</p>	<p>Tell your doctor immediately if you become pregnant while taking this medication.</p>	<ul style="list-style-type: none"> • allergic reaction including skin rash, swelling of the face, lips, tongue or throat, difficulty breathing • thoughts of suicide or attempting suicide or self harm • serotonin syndrome including extremely high fever, muscle stiffness, rapid heartbeat, confusion and coma.
<p>- <u>How long to use it</u> Continue taking Apo-Sertraline for as long as your doctor recommends.</p>	<p>- <u>Things you must not do</u></p>	<p>You might experience the following side effects:</p>
<p>- <u>If you forget to use it</u> Consult your doctor or pharmacist on what you should do if you forget to use it.</p>	<p>Do not stop taking the medicine unless advised by your doctor.</p>	<p><i>Cardiovascular:</i> Blood pressure disturbances</p>
<p>Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.</p>	<p>Your doctor may want you to gradually reduce the amount of Apo-Sertraline you are taking before stopping completely. This should help reduce the chance of withdrawal symptoms (such as dizziness, paraesthesia (tingling sensation), headache, anxiety and nausea)</p>	<p><i>Gastro-intestinal:</i> Vomiting, abdominal pain.</p>
<p>- <u>If you use too much (overdose)</u> Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.</p>	<p>Do not take any new medicines without consulting your doctor or pharmacist.</p>	<p><i>Eye disorders:</i> Abnormal vision.</p>
<p>Symptoms of overdose with sertraline alone included somnolence (drowsiness), nausea, vomiting, tachycardia (increased heart rate),</p>	<p>Do not give Apo-Sertraline to anyone else, even if they have the same symptoms or condition as you.</p>	<p><i>Nervous system:</i> Amnesia (forget things easily), headache, drowsiness, movement disorders, hallucinations (thoughts of things that doesn't exist), aggressive reaction, agitation, anxiety.</p>
	<p>- <u>Things to be careful of</u></p>	<p><i>Seizures:</i> Sertraline should be discontinued in any people who develop seizures.</p>
	<p><i>Driving and using machines</i></p>	<p><i>Musculoskeletal:</i> Muscle or joint pain.</p>
	<p>This medicine may affect your ability to drive or use machines. If the capsules make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.</p>	<p><i>Liver/pancreatic:</i> Rarely, pancreas inflammation and serious liver events.</p>
	<p><i>Suicidality in Children and Adolescent</i></p>	<p><i>Kidney disorders:</i> Urinary Retention</p>
	<p>Apo-Sertraline increases the risk of suicidal ideation and behaviour in children. Despite this, your doctor may prescribe Apo-Sertraline for you or your child when he/she decides that this is in their best interests.</p>	<p><i>Reproductive:</i> Hyperprolactinemia (increased specific hormone), galactorrhoea (excessive or inappropriate</p>
	<p>If your doctor has prescribed Apo-Sertraline for a person under 18 and</p>	

production of milk), menstrual irregularities.

Skin and allergic reactions: Rashes, angioedema (swelling of face, lips, hands and feet.).

Metabolic: Rarely, hyponatremia (low sodium level in your body.)

Haematologic (blood): Altered platelet function and/or abnormal clinical laboratory results have been reported rarely. Thrombocytopenia (low blood platelet count), abnormal bleeding or purpura (bleeding underneath the skin which indicated by reddish-purple spot) in several people taking sertraline has been reported but it is unclear whether sertraline had a causative role.

General: Malaise (feeling discomfort).

Other side effects not listed above may also occur in some people.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of Apo-Sertraline

- Storage

Keep out of the reach and sight of children.

Store between 15-25°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Apo-Sertraline 50 mg are hard gelatin capsules with white opaque body,

yellow opaque cap, imprinted APO 50, and white to off-white powder fill.

Each capsule contains sertraline hydrochloride equivalent to 50 mg sertraline.

- Ingredients

- Active ingredient
Sertraline hydrochloride

- Inactive ingredients
Croscarmellose sodium, stearic acid, colloidal silicon dioxide and starch (corn), talc.

The capsule shells, imprinted with edible black ink, contain the non-medicinal ingredients gelatin, titanium dioxide, D&C yellow #10 and FD&C yellow #6.

- MAL number:

MAL 06071046AZ

Manufacturer

Apotex Inc.
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M9L 1T9 Canada

Product Registration Holder

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