

SERLIFT TABLETS

Sertraline Hydrochloride (50 mg)

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What SERLIFT TABLETS is used for

SERLIFT TABLETS are used in adults for the treatment as well as prevention of relapse/recurrence of:

- Depression
- Panic disorder
- Obsessive compulsive disorder (obsessive thoughts that make you carry out repetitive behaviour)
- Post traumatic stress disorder (condition that can occur after a very emotionally traumatic experience, and has some symptoms that are similar to depression and anxiety)
- Social anxiety disorder (social phobia characterised by feelings of intense anxiety or distress in social situations)

How SERLIFT TABLETS works

SERLIFT TABLETS contain the active ingredient sertraline. Sertraline belongs to a group of medicines called Selective Serotonin Re-uptake Inhibitors (SSRIs); they are thought to work by blocking the uptake of a chemical called serotonin into nerve cells in the brain. Serotonin is involved in controlling mood.

Before you use SERLIFT TABLETS

- When you must not use it

Do not take this medicine if:

- you are allergic to sertraline hydrochloride, or any of the other ingredients in this medication (see Product description).

Some of the symptoms of an allergic reaction may include: rash, itching or hives on the skin, swelling of face, lips,

tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing.

Do not use SERLIFT TABLETS if you are taking pimozone (a medicine used for mental disorders such as psychosis).

Do not use SERLIFT TABLETS if you are taking or have taken medicines called monoamine oxidase inhibitors (MAOIs such as selegiline, moclobemide) or MAOI like medicines (such as linezolid). If you stop treatment with sertraline, you must wait until at least one week before you start treatment with a MAOI. After stopping treatment with a MAOI, you must wait at least 2 weeks before you can start treatment with sertraline. Cases of serious reactions, sometimes fatal, have been reported in people receiving sertraline in combination with a MAOI. Some cases presented with features resembling serotonin syndrome (see section **Side effects**).

- Before you start to use it

Before taking SERLIFT TABLETS your doctor needs to know any other medical condition that you suffer from or have suffered in the past including:

- a history of seizures (fits)
- a history of mania (feeling elated or over-excited, which causes unusual behaviour), hypomania (a condition similar to mania but less severe) or schizophrenia
- a history of bleeding disorders
- low sodium level in your blood, since this can occur as a result of treatment with sertraline. You should also tell your doctor if you are taking certain medicines for high blood pressure, since these medicines may also alter the sodium level in your blood.
- heart conditions causing irregular heartbeats
- liver problems
- diabetes
- eye problems, such as certain kinds of glaucoma (increased pressure in the eye)
- if you are elderly or volume depleted as you may be at more risk of having low sodium level in your blood (see above)

- if you are having electro-convulsive therapy (ECT)

Pregnancy and breastfeeding

The safety of sertraline during pregnancy and lactation has not been established. Do not take SERLIFT TABLETS if you are pregnant, breast-feeding, trying to get pregnant or think you may be pregnant. Ask your doctor or pharmacist for advice before taking any medicine.

If you take SERLIFT TABLETS near the end of your pregnancy particularly in the last 3 months of pregnancy, there may be an increased risk of a serious condition, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. Your newborn baby might also have other conditions, which usually begin during the first 24 hours after birth. Symptoms include trouble with breathing, cool hands and feet, blue lips, vomiting or not feeding properly, being very tired, not able to sleep or crying a lot, stiff or floppy muscles, tremors, jitters or fits, increased reflex reactions, irritability, and low blood sugar. Your doctor should be aware that you are taking SERLIFT TABLETS so they can advise you.

- Taking other medicines

Tell your doctor or pharmacist 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 SERLIFT TABLETS.

These include:

- MAOIs, Pimozone (see **When you must not use it**)
- Fenfluramine (for obesity)
- Tryptophan, an amino acid
- St. John's Wort (a herbal remedy used for depression)
- Tramadol (for moderate to severe pain)
- Sumatriptan or medicines in same class i.e. triptans, 5-HT agonists (used to treat migraine headache).
- Alcohol and grape fruit juice
- Other medicines to treat depression (such as fluoxetine, fluvoxamine, nefazodone etc.)

- Fentanyl (used in anaesthesia or to treat chronic pain)
- Some antipsychotics and antibiotics (medicines known to increase the risk of changes in the electrical activity of the heart)
- Verapamil, diltiazem, flecainide, propafenone (used to treat high blood pressure, chest pain or regulate the rate and rhythm of the heart)
- Warfarin, ticlopidine (for stopping blood from clotting)
- Cimetidine, omeprazole, lansoprazole, pantoprazole, rabeprazole (for heartburn, excessive stomach acid and ulcers)
- Carbamazepine, phenytoin, phenobarbital, valproate (seizure medications)
- Rifampicin, clarithromycin, telithromycin, erythromycin (antibiotics)
- Medicines that affect the brain functions like alertness etc.
- Non-steroidal anti-inflammatory drugs such as aspirin [medicines to treat pain/arthritis]
- Diazepam (sedatives)
- Tolbutamide (medicine to treat diabetes)
- Cisapride (used for constipation)
- Ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole (used to treat fungal infections)
- Protease inhibitors (used to treat HIV/AIDS and Hepatitis C)
- Aprepitant (used to prevent nausea and vomiting after an operation or chemotherapy)
- Antipyrene (used for pain and fever)
- Digoxin (used in heart failure treatment)
- Water tablets (diuretics)
- Lithium (medicine to treat schizophrenia and other mental illness)

If you need a laboratory investigation such as urine test, do inform your doctor/lab personnel that you are taking this medicine.

How to use SERLIFT TABLETS

Follow all directions given to you by your doctor or 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.

- How much to use

Depression and obsessive-compulsive disorder: A dose of 1 tablet/day is recommended as initial dose.

Panic disorder, social anxiety disorder and post-traumatic stress disorder:

The treatment should be started at half tablet/day.

Titration: A gradual increase in dosage may be considered if no clinical improvement is observed. Doses should not exceed a maximum of 4 tablets/day.

Maintenance: 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.

If you are having liver problems, your doctor may decide whether you should have a lower dose of SERLIFT TABLETS.

- How to use it

This medicine should only be taken by mouth.

Swallow your tablets with a glass of water.

- When to use it

It does not matter if you take this medicine before or after food.

Take your medication once daily either in the morning or evening. Your doctor will advise you on the best time of the day to take your tablet.

- How long to use it

Take SERLIFT TABLETS for the duration as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it. Take the missed dose as soon as you remember. If it is almost time for your next dose, do not take the missed dose, but take your next dose at your normal time. Do not take a double dose to make up for the forgotten one.

- If you use too much (overdose)

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.

Symptoms of overdose with sertraline may include drowsiness, nausea and vomiting, rapid heart rate, shaking, agitation, dizziness and in rare cases unconsciousness.

While you are using it

- Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking sertraline.

Tell your doctor immediately, if you become pregnant while taking this medicine.

- Things you must not do

Do not stop taking SERLIFT TABLETS or alter the dose, without first checking with your doctor.

Your doctor may want you to gradually reduce the amount of SERLIFT TABLETS you are taking before stopping completely. This should help reduce the chance of withdrawal symptoms (such as dizziness, numbness, sleep disturbances, headache, feeling sick, being sick, anxiety and shaking).

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours. It may harm them.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. You should therefore not drive or operate machinery, until you know how this medication affects your ability to perform these activities.

Suicidality in Children and Adolescent

Sertraline increases the risk of suicidal ideation and behaviour in children. Signs and symptoms of suicide include thoughts or talk of death or suicide, thoughts or talk of self-harm or harm to others, any recent attempts of suicide or self-harm, increase in aggressive

behaviour, irritability or agitation or worsening of depression. Despite this, your doctor may prescribe SERLIFT TABLETS for you or your child when he/she decides that this is in their best interests.

If your doctor has prescribed SERLIFT TABLETS for a person under 18 years and you want to discuss this, please contact him/her. Families or caregivers should pay close attention to the child whenever SERLIFT TABLETS are started or its dose is changed. Contact your doctor if you notice any sudden or unusual changes in you or your child's behaviour.

Side Effects

Like all medicines, SERLIFT TABLETS may cause side effects, although not everybody gets them.

Nausea is the most common side effect. The side effects depend on the dose and often disappear or lessen with continued treatment.

If you experience the following serious side effects, stop taking SERLIFT TABLETS and tell your doctor immediately or contact the casualty department at your nearest hospital:

- If you develop a severe skin rash that causes blistering (this can affect the mouth and tongue). These may be signs of conditions known as Stevens Johnson Syndrome, or Toxic Epidermal Necrolysis (TEN). Your doctor will stop your treatment in these cases.
- Allergic reaction or allergy, which may include symptoms such as an itchy skin rash, breathing problems, wheezing, swollen eyelids, face or lips.
- If you experience agitation, confusion, diarrhoea, high temperature and blood pressure, excessive sweating and rapid heartbeat. These are symptoms of Serotonin Syndrome. In rare cases this syndrome may occur when you are taking certain medicines at the same time as sertraline. Your doctor may wish to stop your treatment.
- If you develop yellow skin and eyes which may mean liver damage.
- If you experience depressive

symptoms with ideas of harming or killing yourself (suicidal thoughts).

- If you start to get feelings of restlessness and are not able to sit or stand still after you start to take SERLIFT TABLETS. You should tell your doctor
- If you have a fit.

You might experience the following side effects:

The following side effects were seen in clinical trials in adults.

Very common (may affect more than 1 in 10 people):

Sleeping difficulty, dizziness, sleepiness, headache, Inflammation of the colon (causing diarrhoea), feeling sick, dry mouth, ejaculation failure, fatigue.

Common (may affect up to 1 in 10 people):

Sore throat, change of appetite, depression, feeling detachment from one's self, nightmare, anxiety, agitation, nervousness, decreased sexual interest, teeth grinding, numbness and tingling, shaking, tense muscle, abnormal taste, lack of attention, visual disturbance, ringing in ears, palpitations, hot flush, yawning, abdominal pain, vomiting, constipation, indigestion, passing wind, rash, increased sweating, muscle pain, erectile dysfunction, chest pain, joint pain, general discomfort.

Additional side effects in children:

The most common side effects in children were headache, sleeping difficulty, diarrhoea and feeling sick.

An increased risk of bone fractures has been observed in people 50 years of age and older taking this type of medicines.

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

Visit your doctor or pharmacist as soon as possible if you experience any side effects during or after taking SERLIFT TABLETS, so that these may be properly treated.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug

Reaction Monitoring visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of SERLIFT TABLETS

Storage

Store below 30°C, protected from moisture

Keep medicine out of the reach of children

Disposal

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

Product description

What it looks like

Blue coloured film coated oval shaped tablets, embossed with 'SLT' on one side and breakline on the other

Ingredients

Active ingredient:

Sertraline Hydrochloride equivalent to Sertraline ... 50 mg

Inactive ingredients:

Calcium Hydrogen Phosphate, Microcrystalline Cellulose, Polysorbate-80, Hydroxypropyl Cellulose (Low Viscosity), Purified water, Sodium Starch Glycolate (Type A), Magnesium Stearate. For coating: Opadry OY-50922 Blue, Purified Water.

- MAL number(s):

MAL20032261AZ

Manufacturer and Product Registration Holder

RANBAXY (MALAYSIA) SDN. BHD.
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