

SERLIN 50 CAPSULES

Sertraline hydrochloride (50mg)

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What Serlin 50 Capsules is used for

SERLIN can be used to treat:

- Symptoms of depression and prevention of recurrence of depression.
- Obsessive compulsive disorder (OCD) and Panic disorder.

Depression is a clinical illness with symptoms like feeling sad, unable to sleep properly or to enjoy life as you used to.

Obsessive compulsive disorder (OCD) and *Panic disorders* are illnesses linked to anxiety with symptoms like being constantly troubled by persistent ideas (obsessions) that make you carry out repetitive rituals (compulsions).

Your doctor has decided that this medicine is suitable for treating your illness.

You should ask your doctor if you are unsure why you have been given SERLIN.

How Serlin 50 Capsules works

The name of your medicine is Serlin 50 Capsules. It contains the active ingredient, sertraline hydrochloride.

Sertraline is one of a group of medicines called Selective Serotonin Re-uptake Inhibitors (SSRIs).

Serotonin is one of the chemicals in your brain which helps control your mood. Serlin 50 Capsules and other SSRIs are thought to help by increasing the amount of serotonin in your brain.

Before you use Serlin 50 Capsules

- When you must not use it

- Do not take Serlin 50 Capsules if you are allergic (hypersensitive) to sertraline or any of the other ingredients (see section **Product description**).
- If you are taking or have taken medicines called monoamine oxidase inhibitors to treat depression.
- If you stop treatment with sertraline, you must wait until at least two weeks 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.

Pregnancy and lactation

The safety of sertraline has not fully been established in pregnant women. Sertraline will only be given to you when pregnant if your doctor considers that the benefit for you is greater than any possible risk to the developing baby.

There is evidence that sertraline passes into human breast milk. Sertraline should only be used in women during breast-feeding, if your doctor considers that the benefit exceeds any possible risk to the baby.

Child or adolescent under 18 years old SERLIN should only be used to treat children and adolescents aged 6-17 years old. If you are being treated for this disorder, your doctor will want to monitor you closely for clinical worsening, suicidality or unusual changes in behavior.

- Before you start to use it

Medicines are not always suitable for everyone. Tell your doctor before you take SERLIN, if you suffer from or have suffered in the past from any of the following conditions:

- Epilepsy or a history of seizures.
- If you have or have previously had thoughts of harming or killing yourself.

- Liver disease; your doctor may decide that you should have a lower dose of SERLIN.
- Heart attack or unstable heart disease.
- If you are having electro-convulsive therapy (ECT).

- Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription from a pharmacy, supermarket or health food shop.

Some medicines can affect the way SERLIN works, or SERLIN itself can reduce the effectiveness of other medicines taken at the same time.

Talk to your doctor if you are taking the following medicines:

- Blood thinning medicine (warfarin).
- Sedatives (diazepam).
- Medicines to treat diabetes (tolbutamide).
- Medicines to treat excessive stomach acid, ulcers and heartburn (cimetidine).
- Medicines to treat mania and depression (lithium).
- Other medicines to treat depression (such as tricyclic antidepressants).
- Medicines used to regulate the rate and rhythm of the heart (such as flecainide, propafenone).

How to use Serlin 50 Capsules

- How much to use

The usual dose is:

Adults:

Depression and Obsessive Compulsive Disorder: the usual effective dose is 50 mg/day. The daily dose may be increased at intervals of at least one week over a period of weeks. The maximum recommended dose is 200 mg/day.

Panic disorder: Treatment should be started at 25 mg/day, and increased to 50 mg/day after one week.

If you have liver problems, please tell your doctor and follow the doctor's instructions.

- When to use it

Always take SERLIN exactly as your doctor has told you.

SERLIN capsules may be taken with or without food.

Take your medication once daily either in the morning or evening.

Alcohol should be avoided whilst taking SERLIN.

- How long to use it

Your doctor will advise you on how long to take this medication for. This will depend on the nature of your illness and how well you are responding to the treatment. It may take several weeks before your symptoms begin to improve. Treatment of depression should usually continue after improvement.

- If you forget to use it

• If you forget to take your dose, take it as soon as you remember, then continue to take it as usual.

• 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 a forgotten dose.

- 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 may include drowsiness, nausea and vomiting, rapid heart rate, anxiety, and dilated pupils.

While you are using it

- Things you must do

• Tell your doctor immediately if you become pregnant while taking this medication.

• Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor,

pharmacist or nurse if you are not sure.

• Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet. You may need to read it again.

- Things you must not do

• Do not stop taking SERLIN unless your doctor tells you to. Your doctor will want to gradually reduce your dose of Serlin 50 Capsules over several weeks, before you finally stop taking this medicine.

• Do not take any new medicines without consulting your doctor.

• Do not give Serlin 50 Capsules to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Thoughts of suicide and worsening of your depression or anxiety disorder:

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about one week but sometimes longer.

You may be more likely to think like this:

• If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Driving and using machines

Sertraline may influence 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.

Side effects

Like all medicines, SERLIN can cause side effects, although not everybody gets them.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine.

- ejaculation failure, dry mouth, increased sweating
- sleepiness, dizziness, headache
- skin rash
- anorexia (eating disorder), constipation, diarrhea, indigestion, flatulence, nausea, vomiting
- fatigue, hot flushes
- agitation, anxiety, insomnia (unable to sleep), decreased sexual desire, nervousness
- abnormal vision

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

This includes any possible side effects not listed in this leaflet.

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 Serlin 50

Capsules

- Storage

- Store below 25°C. Protect from light.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister after Exp. The expiry date refers to the last day of the month.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Product description

- What it looks like

Serlin 50 Capsules

White to off white granular powder filled in empty hard gelatin capsules with yellow coloured cap and white coloured body.

Blister packs of 28 capsules.

- Ingredients

Each capsule contains:

- Active ingredient

Sertraline hydrochloride 50mg

- Inactive ingredients

Pregelatinised Starch, Sodium lauryl sulfate, Lactose anhydrous, Magnesium stearate.

- MAL number(s):

MAL08051744AZ

Manufacturer

Cadila Healthcare Limited
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Product Registration Holder

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