

SERENATA TABLETS

Sertraline Hydrochloride (50 mg, 100 mg)

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What Serenata is used for

In adults it is used to treat and prevent the recurrence of depression and any connected feelings of anxiety, Obsessive Compulsive Disorder (OCD) and Post Traumatic Stress Disorder (PTSD).

OCD is an illness whereby a persistent (obsessive) unpleasant thought, feeling or action causes anxiety and may make you carry out a repetitive impulse (compulsion).

PTSD is an anxiety disorder caused by the major personal stress of a serious, frightening or traumatic event.

Serenata may help, if you suffer from either OCD or PTSD.

Ask your doctor if you are still unsure why you have been prescribed this medicine.

How Serenata works

Serenata belongs to a group of anti-depressant medicines called Selective Serotonin Reuptake Inhibitors (SSRIs).

They are thought to work by blocking the uptake of a chemical called serotonin into nerve cells in the brain. Serotonin is one of the chemicals that involved in controlling mood.

Before you use Serenata

- When you must not use it

Do not take Serenata if you:

- Are allergic to sertraline, or any of the other tablet ingredients.
- Are taking, or have taken at any time within the last two weeks, any medicines known as Monoamine oxidase inhibitors (also known as MAOIS).

- Have any serious liver problems.
- Are taking a medicine called pimozide.
- Are a child under 18 years old with more severe form of depression.

Pregnancy and lactation

Do not take Serenata if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Serenata if you are breast-feeding as sertraline is known to be found in breast milk. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

You must tell your doctor or pharmacist if you:

- Are breast feeding.
- Have any liver problems (as your dose or frequency of dosing may have to be reduced)
- Have any kidney problems
- Have epilepsy, or have had a fit in the past (as Serenata may increase the risk of a fit).
- Have a history of mania (over active behavior or thoughts) /hypomania (less severe form of mania).
- Are diabetic (as you may need to adjust your dose of insulin or other antidiabetic medication).
- Are having ECT (electroconvulsive therapy) treatment.
- Have a history of bleeding disorders.

- 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 of the recorded interaction of medicines with Sertraline are:

- Lithium, tryptophan, another antidepressant or anti obsessional medicines.
- Tramadol (a painkiller), sumatriptan (for migraine), fenfluramine (for suppressing appetite).
- Warfarin (used to thin the blood), Diazepam (for anxiety relief), tolbutamide (for diabetes), or cimetidine (for ulcers).

- Aspirin or NSAIDs (nonsteroidal anti-inflammatory medicine) including those that may have been bought without a prescription.
- St. John's Wort (a herbal remedy).
- Alcohol should be avoided whilst taking this medicine.

How to use Serenata

- How much to use

Always follow your doctor's instructions exactly, and those printed on the pharmacy label.

The usual dosages are listed below. If you have been prescribed a dose that is different from that below you should discuss it with your doctor, if you haven't already done so.

Adults:

Depression and Obsessive Compulsive Disorder (OCD): The usual dose at the start of treatment is 50 mg daily; however your doctor may decide to increase the dose 50 mg at a time. up to a maximum of 200 mg daily

Post-traumatic stress disorder (PTSD):

The usual dose at the start of treatment is 25 mg (half a 50 mg tablet) daily, increasing after one week to 50 mg daily. Larger doses may also be prescribed, up to a maximum of 200 mg daily.

Adults with poor liver function:

If you have impaired liver function your doctor may prescribe lower dosage of Serenata than the usual stated above, or prescribe a less frequent dose.

Children:

The safety and effectiveness of sertraline in children have not been fully established.

- When to use it

Each dose should be swallowed with a drink of water, with or without food. Do not chew or crush the tablets. To help you to remember to take your medicine regularly it is recommended that you try and take each dose at the same time each day.

- How long to use it

Continue taking Serenata for as long as your doctor recommends as you may need to keep taking the tablets to stay

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well even when if you start to feel better.

- If you forget to use it

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. In that case, just carry on with the next dose as normal. 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.

Taking too many tablets may cause:

- Sleepiness.
- Nausea.
- Vomiting.
- Abnormally fast heartbeat.
- Shaky.
- Agitation.
- Dizziness.
- Less frequently coma.

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists that are treating you that you are taking Serenata.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking your medicine unless your doctor tells you to do so. Your doctor will tell you to discontinue treatment with sertraline periodically. Common discontinuation symptoms included dizziness, 'pins and needles' sensation, headache, anxiety and nausea.
- Do not take any new medicines without consulting your doctor.
- Do not give Serenata to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

You may need to take Serenata tablets for up to 2-4 weeks before you start to

feel better and for the full antidepressant effect of this medicine to become noticeable. During this time the symptoms of depression, which may include thoughts of suicide or self-harm, may remain or increase.

Tell your doctor immediately if you experience these symptoms.

- Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders.
- If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

People who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised to closely observe the individual and to communicate with the prescriber.

Driving and using machines

Dizziness, tiredness, and vision problems may occur during treatment with Serenata. Do not drive or use any tools or machines without talking to your doctor first.

Side effects

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

An allergic reaction which may occur as:

- Swelling of the eyelids, lips, face, mouth, hands or feet
- A rash on your skin (which might be severe).
- Sudden wheeziness or tightness in the chest.
- Skin lumps and hives.

Some of the side effects are:

- Allergic reaction. If you think you are having an allergic reaction stop taking your tablets immediately and tell your doctor or go to your local hospital emergency department as severe allergic reactions may require emergency treatment.
- Convulsions or fits.

- Liver disorders (including abnormal liver function tests) or yellowing of the skin and whites of the eyes.
- Severe pain in the stomach and/or back (which may be caused by an inflamed pancreas).
- Changes to your blood pressure, including low blood pressure (which may cause you to feel dizzy or unsteady).
- Blood disorders, including an decrease in the number of platelets, easy bruising or bleeding, change in platelet functioning and abnormal blood tests.
- A collection of symptoms called "Serotonin syndrome" which can include fever, feels of confusion, agitation or anxiety, sweating, faster heartbeat and diarrhoea.
- Psychological effects such as hallucinations (hear, smell, taste or feel things that do not exist), aggression, loss of contact with reality, a feel of being detached from yourself, nervousness or panic.
- Abnormal vision.
- Lowering of blood sodium levels (which may make you tired, weak, headache or muscle cramp).
- Vomiting or feeling sick.
- Shaky.
- Loss of appetite.
- Inability to go to sleep or sleepiness.
- Not being able to pass urine.
- Change in sexual function (e.g. ejaculatory delay in men).
- Sensitivity to sunlight.
- Menstrual irregularities.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Tell your doctor if you get any side effect that bothers you or that does not go away.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects (ConSERF) or Vaccine (AEFI)).

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Storage and Disposal of Serenata**Storage**

- Store below 30°C.
- Keep out of reach and sight of children

Date of revision

08/08/2018

Serial Number

NPRA(R4/1)080818/00231

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**

White to off white capsule shaped, biconvex film coated tablets with bisecting line on one side.

Ingredients

Active ingredient:

- Sertraline Hydrochloride.

Inactive ingredients:

- Microcrystalline cellulose.
- Sodium starch glycollate.
- Calcium hydrogen phosphate dihydrate.
- Hydroxypropylcellulose.
- Polysorbate 80.
- Magnesium stearate.
- Hypromellose.
- Propylene glycol.
- Titanium dioxide.

MAL number(s):**SERENATA TABLETS 50MG:**

MAL07081476AZ

SERENATA TABLETS 100MG:

MAL07081477AZ

Manufacturer

Torrent Pharmaceuticals Limited
Indrad 382 721, Tal: Kadi,
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Product Registration Holder

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