

# AURASERT TABLETS

Sertraline (50mg, 100mg)

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## What AURASERT is used for

- For the treatment of symptoms of depressive illness including accompanying symptoms of anxiety. It is also indicated in preventing relapse of the initial episode of depression or recurrence of further depressive episodes including accompanying symptoms of anxiety.
- In the treatment of obsessions (persistent, obsessive thoughts) and compulsions (uncontrollable, repetitive behavior) in patients with obsessive compulsive disorder (OCD).
- For the treatment of panic disorder with or without agoraphobia (fear of public or open spaces).

## How AURASERT works

AURASERT contains the active ingredient Sertraline and 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. Sertraline blocks the reabsorption of serotonin by the nerve cells, thereby increasing the amount of serotonin in your brain.

## Before you use AURASERT

- When you must not use it

Do not take sertraline if:

- You are allergic to sertraline or any of the other ingredients of this medicine (see section **Product Description**).
- You are taking or have recently taken medicines called monoamine oxidase

inhibitors (MAOIs, including selegiline and moclobemide) or MAOI like drugs (such as linezolid).

- AURASERT should not be used concomitantly to patients taking monoamine oxidase inhibitors, while switching from an MAOI to sertraline or vice-versa, a washout period of at least 14 days should elapse.

Taking Sertraline with a MAOI may cause a serious, fatal reaction with features resembling neuroleptic malignant syndrome. The symptoms may include a sudden increase in body temperature, muscle stiffness, extremely high blood pressure, confusion, extreme restlessness and coma.

- Before you start to use it

Talk to your doctor before taking Sertraline, if you suffer from or have suffered in the past from any of the following conditions:

- If you have epilepsy or a history of fits (seizures).
- If you have suffered from manic depressive illness (bipolar disorder i.e. extreme mood swings ranging from episodes of depression to mania or excessive excitement) or schizophrenia (a severe brain disorder in which people interpret reality abnormally). If you have a manic episode, contact your doctor immediately.
- If you have or have previously had thoughts of harming or killing yourself.
- If you have liver or kidney problems.
- If you are a child or adolescent under 18 years old.
- If you are having electroconvulsive therapy (ECT), usually used for severe depression.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- Taking other medicines

- Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.
- Some medicines can affect the way Sertraline works, or Sertraline itself can reduce the effectiveness of other medicines taken at the same time.

These include:

- MAOIs (see when you must not use it)
- Other medicines for depression, such as tricyclic antidepressants (TCAs)
- Medicines used to relieve anxiety such as diazepam
- Medicines used to treat mental illness, such as lithium,
- Blood-thinning medicines, such as warfarin.
- Medicines used to treat heart conditions such as digoxin propafenone, flecainide

Other medicines not listed above may also interact with sertraline.

## How to use AURASERT

- How much to use

### Adults:

### Depression and Obsessive Compulsive Disorder

- For depression and OCD, the usual effective dose is 50 mg/day. The daily dose may be increased in 50mg increments and at intervals of at least one week over a period of weeks.
- The maximum recommended dose is 200 mg/day.

### Panic disorder

- For panic disorder, treatment should be started at 25 mg/day, and increased to 50mg/day after one week.
- The maximum recommended dose is 200 mg/day.

If you are an elderly or if you have liver problems, your doctor may decide that you should have a lower dose of Sertraline.

- When to use it

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

- How long to use it

Continue taking AURASERT for as long as your doctor recommends.

- If you forget to use it

- If you forget to take a dose, do not take the missed dose. Just take the next dose at the right time.
- Do not take a double dose to make up for a forgotten dose.
- If you are not sure what to do, ask your doctor or pharmacist.

- If you use too much (overdose)

- If you accidentally take too much Sertraline, contact your doctor at once or go to the nearest hospital casualty department. Always take the labelled medicine package with you, whether there is any medication left or not.
- Symptoms of overdose may include drowsiness, nausea and vomiting, and rapid heart rate.

**While you are using it**

- Things you must do

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

Tell your doctor or pharmacists immediately if:

- You become pregnant while taking this medication.
- You have new episodes of fits.

- Things you must not do

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

Do not take your medicine to treat any other condition unless your doctor or pharmacist tells you to.

Do not stop taking Sertraline, or lower the dose, without first checking with

your doctor. Your doctor may want you to gradually reduce the amount of Sertraline you are taking before stopping completely.

- Things to be careful of

*Driving and using machines*

Psychotropic drugs such as 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. Concomitant use of alcohol with sertraline should be avoided.

*Suicidality in Children and Adolescent*

Sertaline should normally not be used for children and adolescents under 18 years. Sertraline should only be used to treat children and adolescents aged 6-17 years old, suffering from obsessive compulsive disorder (OCD). Sertaline increases the risk of suicidal ideation and behaviour in children. If you or your children are being treated for this disorder, your doctor will want to monitor you closely.

If your doctor has prescribed Sertaline for a patient under 18 and you want to discuss this, please go back to your doctor. Families or caregivers should pay close attention to your child whenever Sertaline is started or its dose is changed. Contact your doctor if you notice any sudden or unusual changes in your child's behaviour.

**Side effects**

If you experience any of the following symptoms after taking this medicine, tell your doctor immediately as these symptoms can be serious.

If you experience allergic reaction or allergy, which may include symptoms such as an itchy skin rash, breathing problems, wheezing, swollen eyelids, face, lips or a severe skin reaction that causes blistering.

If you experience symptoms resembling neuroleptic malignant syndrome (*see when you must not use it*).

If you experience depressive symptoms with ideas of harming or killing yourself (suicidal thoughts).

If you start to get feelings of restlessness and not able to sit or stand still after you start to take Sertraline.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Nausea,
- diarrhea,
- vomiting,
- anorexia (an eating disorder characterised by self-starvation and excessive weight loss),
- abdominal cramps,
- tremor,
- anxiety,
- agitation,
- dizziness,
- nervousness,
- blurred vision,
- dryness of mouth,
- Palpitations (abnormally rapid or violent beating of the heart).

Other side effects not listed above may also occur in some people. Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

**Storage and Disposal of AURASERT**

- Storage

Store below 30°C.

- 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 protect the environment

**Product Description**

- What it looks like

AURASERT TABLETS 50mg

White colored, biconvex, capsule shaped film-coated tablets marked with 'A' on

one side and with a score line between '8' and '1' on the other side.

**AURASERT TABLETS 100 mg**

White colored, biconvex, capsule shaped, film-coated tablets marked with 'A' on one side and '82' on the other side.

- Ingredients

- Active ingredient

Sertraline

- Inactive ingredients

Sodium starch glycolate (Type A),  
Purified water, Magnesium Stearate,  
Calcium hydrogen phosphate  
dehydrate, Opadry White,  
hydroxypropylcellulose, Avicel PH  
101 (Microcrystalline Cellulose).

- MAL number(s):

- AURASERT TABLETS 50mg  
MAL10012450AZ
- AURASERT TABLETS 100 mg  
MAL10012451AZ

**Manufacturer**

**Aurobindo Pharma Limited**

Unit-III, Survey no.313, Bachupally  
Village, Quthubullapur Mandal, R.R.  
District, Andhra Pradesh, India.

**Product Registration Holder**

**UNIMED SDN BHD**

No.53 Jalan Tembaga SD 5/2B,  
Bandar Sri Damansara,  
52200 Kuala Lumpur

**Date of revision**

24/08/2015

**Serial Number**

BPFK (R4/1)240815/00274