

AURO-SERTRALINE 50 & 100

Sertraline (as hydrochloride)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about AURO-SERTRALINE.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

Your doctor has weighed the risks of you taking AURO-SERTRALINE against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT AURO-SERTRALINE IS USED FOR

AURO-SERTRALINE is used to treat depression and conditions called obsessive compulsive disorder (OCD), panic disorder, social phobia (social anxiety disorder) and premenstrual dysphoric disorder (PMDD).

PMDD affects some women in the days before their period. PMDD is different from premenstrual syndrome (PMS). The mood symptoms (anger, sadness, tension, etc) in PMDD are more severe than in PMS and affect the woman's daily activities and relationships with others.

AURO-SERTRALINE belongs to a group of 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 and other chemicals called amines are involved in controlling mood.

Your doctor, however, may prescribe AURO-SERTRALINE for another purpose.

Ask your doctor if you have any questions about why AURO-SERTRALINE has been prescribed for you.

This medicine is only available with a doctor's prescription.

There is no evidence that AURO-SERTRALINE is addictive.

BEFORE YOU TAKE AURO-SERTRALINE

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When you must not take it

Do not take AURO-SERTRALINE if:

- You have ever had an allergic reaction to AURO-SERTRALINE or any of the ingredients listed at the end of this leaflet.** Some of the symptoms of an allergic reaction to AURO-SERTRALINE may include a skin rash, itchiness, difficulty breathing and swelling of the face.
- You have epilepsy not properly controlled by medication.**

- You are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking it within the last 14 days.**

Taking AURO-SERTRALINE with a MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and convulsions (fits).

- You are taking phentermine (used to help weight loss), tryptophan, tramadol or medicines used to treat migraine, eg sumatriptan (Imigran).**

These medicines can cause an exaggerated response to AURO-SERTRALINE.

- You are taking pimozone (used to treat disturbances in thinking, feeling and behaviour).**

Ask your doctor or pharmacist if you are not sure if you have been taking one of these medicines.

Do not give AURO-SERTRALINE to children unless the doctor has prescribed it for the treatment of OCD.

AURO-SERTRALINE is not suitable for children under 6 years of age.

Do not take AURO-SERTRALINE if:

- the expiry date marked on the packaging has passed, even though the tablets may look alright.
- the packaging is torn or shows signs of tampering.

If this is the case, take the tablets to your pharmacist.

Before you start to take it

Tell your doctor if:

You are allergic to any foods, dyes, preservatives or any other medicines

You have any health problems, including:

- any other mental illness
- epilepsy or seizures
- liver or kidney problems
- a tendency to bleed more than normal

You are pregnant or intend to become pregnant

The effects of AURO-SERTRALINE on the developing baby are not yet known.

There have been reports that babies exposed to AURO-SERTRALINE and other antidepressants during the second or third trimester of pregnancy may develop complications after birth.

You are breastfeeding or wish to breastfeed

AURO-SERTRALINE passes into breast milk and may affect your baby.

Your doctor will discuss the risks and benefits of using AURO-SERTRALINE when pregnant or breastfeeding.

Taking other medicines

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

Some medicines should not be taken with AURO-SERTRALINE.

These include:

- other medicines for the treatment of depression called monoamine oxidase inhibitors (MAOIs).

Taking AURO-SERTRALINE with, or within 14 days of stopping a MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and convulsions.

- Medicines that can increase the effects of AURO-SERTRALINE such as tramadol, tryptophan, or phentermine (weight-reducing medicines) and medicines used to treat migraine, eg sumatriptan.

- Pimozone (used to treat disturbances in thinking, feeling and behaviour)

You may respond differently to AURO-SERTRALINE, or to some other medicines, if you take them together. These include (not all brands given):

- other medicines for depression, panic disorder, social anxiety disorder or obsessive illnesses (eg Prothiaden, Pertofran, Prozac, Aropax, Luvox, Cipramil, Efexor)

- other medicine for PMDD (eg Prozac and Lovan)

- St John's wort, a herbal remedy used to treat mood disorders

- clozapine, (eg Clozaril) a medicine used to treat schizophrenia

- medicines for irregular heart beat (eg Tambocor)

- warfarin (eg Marevan, Coumadin) or other medicines that stop the blood from clotting

- medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis (eg aspirin or NSAIDs such as ibuprofen or diclofenac)

- lithium (eg Lithicarb), a medicine used to treat mood swings

- phenytoin (eg Dilantin), a medicine used to treat epilepsy

- sumatriptan (eg Imigran), a medicine used to treat migraine

- diazepam or other medicines that act on the brain or nervous system (eg Serepax and Valium)

- cimetidine (eg Tagamet), a medicine used to treat reflux and ulcers

- tolbutamide (eg Rastinon), a medicine used to treat diabetes

- methadone, a medicine used to treat drug addiction

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking AURO-SERTRALINE.

If you have not told your doctor or pharmacist about these things, tell them before you start taking AURO-SERTRALINE.

HOW TO TAKE AURO-SERTRALINE

Take AURO-SERTRALINE exactly as your doctor has prescribed.

Follow all directions given to you by your doctor. They may differ from the information contained in this leaflet.

How much to take

For **DEPRESSION IN ADULTS** the usual starting dose for AURO-SERTRALINE is one 50 mg tablet each day. The dose can be increased gradually up to 200 mg a day if necessary.

For **OBSESSIVE COMPULSIVE DISORDER IN CHILDREN (6-12 YEARS)** the usual starting dose for AURO-SERTRALINE is 25 mg/day (half a 50mg tablet), increasing to 50 mg/day after one week.

For **OBSESSIVE COMPULSIVE DISORDER IN ADULTS AND ADOLESCENTS (13 18 YEARS)** the usual starting dose for AURO-SERTRALINE is one 50 mg tablet eachday.

For **PANIC DISORDER IN ADULTS** the usual starting dose for AURO-SERTRALINE is 25 mg per day, increasing to 50 mg per day after one week.

For **SOCIAL PHOBIA (SOCIAL ANXIETY DISORDER) IN ADULTS** the usual starting dose for AURO-SERTRALINE is 25 mg per day, increasing to 50 mg per day after one week.

The maximum recommended dose of AURO-SERTRALINE for the conditions listed above is 200 mg per day.

For **PREMENSTRUAL DYSPHORIC DISORDER** the usual starting dose for AURO-SERTRALINE is one 50 mg tablet each day, either throughout the menstrual cycle (to a maximum of 150 mg daily) or for the last 14 days before the start of menses (to a maximum of 100 mg daily).

However, depending on your condition and how you react to the medicine, your doctor may ask you to take some other dose.

How to take it

Swallow the tablet(s) with a glass of water.

Try to take your tablet(s) at the same time each day, either morning or evening.

AURO-SERTRALINE can be taken with or without food.

How long to take it

Most medicines for depression and obsessive illnesses take time to work, so do not be discouraged if you do not feel better straight away.

It may take 2 to 4 weeks or even longer to feel the full benefit of AURO SERTALINE.

Even when you feel well, you may need to take AURO SERTALINE for several months or longer. Continue taking AURO SERTALINE until your doctor tells you to stop.

If you have PMDD, your doctor may ask you to take this medicine only at certain times of the month.

Do not stop taking AURO SERTALINE, or change the dose, without first checking with your doctor.

If you forget to take it

Do not take an extra dose. Wait until the next day and take your normal dose then.

Do not try to make up for the dose you missed by taking more than one dose at a time.

If you take too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency (Casualty) at your nearest hospital if you think you or anyone else may have taken too much AURO-SERTRALINE, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you take too many tablets, you may feel drowsy, sick in the stomach, have a fast heart beat, suffer from tremors, feel agitated or dizzy. Coma has also been reported with overdose.

WHILE YOU ARE TAKING AURO-SERTRALINE

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking AURO-SERTRALINE.

Tell your doctor or pharmacist that you are taking AURO-SERTRALINE if you are about to be started on any new medicines.

Tell your doctor if you become pregnant while taking AURO-SERTRALINE.

If you are a woman of child-bearing age, you should avoid becoming pregnant while taking AURO-SERTRALINE.

Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.

A worsening of depressive symptoms including thoughts of suicide or self harm may occur in the first one or two months of you taking AURO-SERTRALINE or when the doctor changes your dose. These symptoms should be controlled when the full effect of AURO-SERTRALINE takes place.

Children, adolescents or young adults under 24 years of age are more likely to experience these effects during the first few months of treatment.

If you or someone you know is demonstrating any of the following warning signs of suicide while taking AURO-SERTRALINE, contact your doctor or a mental health professional right away or go to the nearest hospital for treatment:

- Thoughts or talk of death or suicide
- Thoughts or talk of self-harm or harm to others
- Any recent attempts of self-harm
- Increase in aggressive behaviour, irritability or agitation
- Worsening of depression

All mentions of suicide or violence must be taken seriously.

Things you must not do

Do not stop taking AURO-SERTRALINE, or change the dose, without first checking with your doctor.

Do not let yourself run out of tablets over the weekend or on holidays.

Suddenly stopping AURO-SERTRALINE may cause dizziness, lightheadedness, numbness, unusual tingling feelings or shakiness.

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

Do not use AURO-SERTRALINE to treat any other complaints unless your doctor says to.

Things to be careful of

Be careful driving or operating machinery until you know how AURO-SERTRALINE affects you.

Some medicines for depression may affect your ability to drive or operate machinery or do things that could be dangerous if you are not alert.

Although drinking moderate amounts of alcohol is unlikely to affect your response to AURO-SERTRALINE, your doctor may suggest avoiding alcohol while you are taking AURO-SERTRALINE.

You should wait at least 14 days after stopping AURO-SERTRALINE before starting medicines for depression or obsessive illnesses from the MAOI group, such as Aurorix, Eldepryl, Nardil and Parnate.

All of the above precautions are important even after you have stopped taking AURO-SERTRALINE.

The effects of AURO-SERTRALINE may last for some days after you have stopped taking it.

SIDE EFFECTS

Check with your doctor as soon as possible if you have any problems while taking AURO-SERTRALINE, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, AURO-SERTRALINE can cause some side effects. If they occur, most are likely to be minor and temporary.

However, some may be serious and need medical attention.

Tell your doctor immediately, or go to your nearest hospital if you notice any of the following:

- fits or seizures
- signs of allergy such as rash or hives, swelling of the face, lips or tongue, wheezing or difficulty breathing
- symptoms of sudden fever with sweating, fast heart beat and muscle stiffness, which may lead to loss of consciousness
- palpitations or chest pain
- abnormal bleeding
- difficulty in passing urine or blood in the urine
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- fever, sore throat, swollen glands, mouth ulcers, unusual bleeding or bruising under the skin
- symptoms of agitation, anxiety, confusion, dizziness, feeling tense and restless, feeling of tiredness, drowsiness, or lack of energy, headache, irritability, nausea, trouble sleeping and tingling or numbness of the hands and feet after stopping AURO-SERTRALINE.

These symptoms are usually rare but may be serious and need urgent medical attention.

Tell your doctor if you experience:

- headache, dizziness, shakiness, muscle stiffness or weakness, decrease or loss of touch or other senses
- dry mouth, increased sweating, feeling sick, diarrhoea, indigestion, vomiting, constipation & stomach pain
- tiredness, hot flushes, fever, feeling unwell
- weight increase or loss
- sleeping difficulties, sleepiness

- sexual problems
- agitation, nervousness, anxiety, frightening dreams, yawning, abnormal thinking, teeth grinding, loss of appetite, impaired concentration
- vision disturbance
- menstrual irregularities
- loss of control of your bladder
- unusually overactive
- shaking or tremors
- unusual hair loss or thinning
- swelling of hands, ankles or feet
- tingling or numbness of the hands or feet
- breast enlargement in men or the unusual secretion of breast milk in men or women
- increased sensitivity of the skin to sun
- ringing or other persistent noise in the ears

These side effects are usually mild.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you do not understand anything in this list.

- AURO-SERTRALINE 100 mg - 100 mg sertraline per tablet

Other ingredients

- cellulose microcrystalline,
- calcium hydrogen phosphate, hydroxypropylcellulose,
- sodium starch glycolate type-A, magnesium Stearate and white opadry (contains hypromellose, macrogol 400, titanium dioxide & polysorbate 80)

AURO-SERTRALINE does not contain gluten, lactose or sugar.

Name and Address of the Sponsor

Aurobindo Pharma Australia Pty Ltd
Unit 3, North Rydelink
277-283 Lane Cove Road
Macquarie Park NSW 2113
Australia

Date of Approval

TGA approval: 19 March 2009.

Date of most recent amendment: 11 May 2011

AFTER TAKING AURO-SERTRALINE

Storage

Keep your tablets where young children cannot reach them.

A locked cupboard at least 1 ½ meters above the ground is a good place to store medicines.

Keep AURO-SERTRALINE in a cool, dry place where the temperature stays below 25°Celsius. Do not store it or any other medicine in the bathroom or near a sink .

Do not leave it in the car or on window sills.
Heat and dampness can destroy some medicines.

Keep your tablets in their blister pack until it is time to take them.

Disposal

If your doctor tells you to stop taking AURO-SERTRALINE, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

PRODUCT DESCRIPTION

What it looks like

AURO-SERTRALINE tablets come in 50 mg & 100 mg:

AURO-SERTRALINE comes in pack size of 30 tablets.

- **AURO-SERTRALINE 50 (AUST R 149396)**
White coloured, biconvex, capsule shaped film coated tablets, debossed with 'A' on one side and with a score line in between '8' and '1' on the other side.
- **AURO-SERTRALINE 100 (AUST R 149401)**
White coloured, biconvex, capsule shaped film coated tablets, debossed with 'A' on one side and '82' on the other side.

Ingredients

Active ingredients

- AURO-SERTRALINE 50 mg - 50 mg sertraline per tablet