

APO-Sertraline Tablets

Contains the active ingredient sertraline (as sertraline hydrochloride)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about sertraline. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Sertraline. It contains the active ingredient sertraline (as sertraline hydrochloride).

It is used to treat:

- depression
- social anxiety disorder or social phobia
- Pre-Menstrual Dysphoric Disorder (PMDD)

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

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

How it works

Sertraline belongs to 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 and other SSRIs are thought to help by increasing the amount of serotonin in your brain.

Depression is longer lasting and/or more severe than the "low moods" everyone has from time to time due to the stress of everyday life. It is thought to be caused by a chemical imbalance in parts of the brain. This imbalance affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, being unable to enjoy life, poor appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty over nothing.

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 relationship with others.

There is no evidence that this medicine is addictive.

Clinical experience has shown that sertraline should not affect the ability to drive or operate machinery. However, make sure you know how sertraline affects you before driving or operating machinery, as it can make some people drowsy or dizzy or affect their concentration.

Use in children

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are taking any of the following medicines:**
 - Pimozide (used to treat disorders which affect the way you think, feel or act)
 - Monoamine Oxidase Inhibitors (MAOIs), used to treat depression (phenelzine, tranylcypromine, moclobemide), Parkinson's Disease (selegiline) or infections (linezolid).
- **Do not take sertraline until 14 days after stopping any MAOI, and do not take MAOIs until 14 days after stopping sertraline.**

Taking sertraline with MAOIs may cause a serious reaction with signs such as a sudden increase in body temperature, very high blood pressure, rigid muscles, nausea/vomiting and/or fits (convulsions). Your doctor will know when it is safe to start sertraline after the MAOI has been stopped.

- **You have had an allergic reaction to sertraline or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, rash, itching or hives on the skin; fainting or hayfever-like symptoms

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - mania, hypomania, bipolar disorder or any other conditions which affect the way you think, feel or act
 - epilepsy or convulsions, fits or seizures (you should avoid taking sertraline if your epilepsy is not properly controlled; if it is properly controlled your doctor will wish to watch you carefully if you take sertraline)
 - heart problems
 - liver problems
 - kidney problems

- problems with blood clotting or abnormal bleeding
 - thoughts or actions relating to self-harm or suicide.
3. You are currently pregnant or you plan to become pregnant. It is not recommended that you take this medicine whilst pregnant. The effects of sertraline on the developing baby are not yet known. There have been reports that babies exposed to sertraline and other antidepressants during the third trimester of pregnancy may develop complications after birth. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
 4. You are currently breast-feeding or you plan to breast-feed. Sertraline passes into breast milk and may affect your baby. Do not take this medicine whilst breast-feeding until you and your doctor have discussed the risks and benefits involved.
 5. You are planning to have, or have recently had, surgery or an anaesthetic.
 6. You are currently receiving or are planning to receive dental treatment.
 7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some combinations of medicines may increase the risk of serious side effects and are potentially life-threatening. Therefore some medicines must not be taken with sertraline. These include:

- monoamine oxidase inhibitors, such as moclobemide, phenelzine, tranylcypromine, selegiline and linezolid
- pimozide

Some other medicines may interact with sertraline. These include:

- phentermine, a weight loss medicine
- tryptophan, contained in some multivitamin and herbal preparations
- tramadol, a strong pain-killer
- sumatriptan, naratriptan and zolmitriptan, used for treating migraines
- St John's Wort (Hypericum perforatum), a herbal remedy for mood disorders
- other SSRIs (e.g. fluoxetine, citalopram, paroxetine, fluvoxamine)
- other medicines for depression, mood disorders or social anxiety disorder, such as dothiepin, desipramine, amitriptyline, lithium and venlafaxine
- medicines called antipsychotics, used to treat psychoses, schizophrenia and other conditions which affect the way you think, feel or act
- prochlorperazine, used to prevent or treat severe nausea and vomiting
- phenytoin, used to control epilepsy or fits
- medicines used to treat heart conditions, such as flecainide and propafenone
- medicines called diuretics, used to get rid of excess fluid from the body, and to treat high blood pressure
- medicines known to prolong bleeding, e.g. aspirin, other non-steroidal anti-

inflammatory drugs (NSAIDs) and anti-coagulants (such as warfarin), which can thin the blood

- cimetidine, used to treat stomach ulcers or reflux
- methadone, a medicine used to treat drug addiction
- diazepam, a medicine used to treat anxiety disorders

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with sertraline.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Adults (18 years and older)

For Depression

The usual starting dose for sertraline is one 50 mg tablet each day. The dose can be increased gradually up to 200 mg a day if necessary.

For Social Phobia (Social Anxiety Disorder)

The usual starting dose for sertraline is 25 mg per day (half a 50 mg tablet), increasing to 50 mg per day after one week.

The maximum recommended dose of sertraline for the treatment of social phobia is 200 mg per day.

For Pre-Menstrual Dysphoric Disorder (PMDD)

The usual starting dose for 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 your period (to a maximum of 100 mg daily).

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow the tablets with a glass of water.

When to take it

Take your tablets once a day, either in the morning or in the evening.

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Most antidepressants take time to work, so don't be discouraged if you don't feel better right away. Some of your symptoms may improve in 1 or 2 weeks but it can take up to 4 to 6 weeks to feel any real improvement. Even when you feel well, you will usually have to take sertraline for several months or even longer to make sure the benefits will last.

Make sure you have enough to last over weekends and holidays.

Occasionally the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. It is possible that these symptoms may continue or

increase until the full anti-depressant effect of your medicine becomes apparent (i.e. one to two months).

You or anyone close to you or caring for you should watch for these symptoms and tell your doctor immediately or go to the nearest hospital if you have any distressing thoughts or experiences during this initial period or at any other time.

Also contact your doctor if you experience any worsening of your depression or other symptoms at any time during your treatment.

Stopping Treatment

Do not stop taking this medicine even if you begin to feel better.

Your doctor may decide that you should continue to take it for some time, even when you have overcome your problem. For best effect, this medicine must be taken regularly.

Your doctor will tell you when and how this medicine should be discontinued. Your doctor will usually recommend that you stop treatment by slowly reducing the dosage over a period of several weeks. When you stop treatment with this medicine especially if this is done suddenly, you may experience unwanted side effects such as headache, feeling dizzy, sick, irritable, agitated, lethargic or anxious; sweating; pins and needles or electric shock feelings, changing moods or emotions, or disturbed sleep if sertraline is stopped, particularly if stopped suddenly.

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 take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much sertraline, you may have some of the following symptoms: sedation, nausea, diarrhoea, vomiting, fast heartbeat, tremor, agitation, dizziness and unconsciousness.

While you are taking this medicine

Things you must do

People taking sertraline may be more likely to think about killing themselves or actually try to do so, especially when sertraline is first started or the dose is changed. Tell your doctor immediately if you have thoughts about killing yourself or if you are close to or care for someone using sertraline who talks about or shows signs of killing him or herself.

All mentions of suicide or violence must be taken seriously.

Occasionally, the symptoms of depression may include thoughts of suicide or self-harm. It is possible that these symptoms continue or get worse during the first one to two months of taking sertraline until the medicine starts to work completely. This is more likely to occur if you are

a young adult, i.e. 18 to 24 years of age, and you have not used antidepressant medicines before.

If you or someone you know or care for demonstrates any of the following warning signs of suicide-related behaviour while taking sertraline, contact a doctor immediately, or even go to the nearest hospital for treatment:

- thoughts or talk of death or suicide
- thoughts of talk of self-harm or harm to others
- any recent attempts of suicide or self-harm
- increase in aggressive behaviour, irritability or agitation
- worsening of depression.

Tell your doctor immediately if you become pregnant.

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

Make sure your midwife and/or doctor know you are taking sertraline. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like sertraline may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

Some people (especially older people or those taking diuretics/water tablets) may experience a lack of sodium in the blood when taking this medicine. Tell your doctor if you get a headache or start to feel dizzy, confused, forgetful, weak, unsteady or unable to concentrate.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are breast-feeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the tablets are not helping your condition.

If you are being treated for depression, be sure to discuss with your doctor any problems you may have and how you feel, especially any feelings of severe sadness, thoughts of suicide, bursts of unusual energy, anger or aggression, or if you become particularly agitated or restless.

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

Make sure you have enough tablets to last over weekends and holidays.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours

- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor. If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects (see "Things to be careful of").

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

This medicine may cause dizziness, drowsiness or impaired concentration in some people. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking sertraline.

If you drink alcohol, dizziness, drowsiness or impaired concentration may be worse.

Although drinking moderate amounts of alcohol is unlikely to affect your response to this medicine, your doctor may suggest avoiding alcohol while you are being treated with this medicine.

You should wait at least 14 days after stopping sertraline before starting any medicines known as monoamine oxidase inhibitors (MAOIs), such as selegiline, phenelzine, tranylcypromine, moclobemide and linezolid.

The effects of sertraline may last for some days after you have stopped taking it.

When your doctor decides that you should stop taking this medicine, the dose may be reduced slowly or the time between the doses increased over 1 to 2 weeks.

Some people may have symptoms such as headache, feeling dizzy, sick, irritable, agitated, lethargic or anxious; sweating; pins and needles or electric shock feelings, changing moods or emotions, or disturbed sleep if sertraline is stopped, particularly if stopped suddenly.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking sertraline or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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

This list includes the more common side effects. Mostly, these are mild:

- feeling tired and weak (fatigued), hot flushes, fever, feeling unwell, shaking or tremors, headache, dizziness
- muscle pain, stiffness, weakness or cramps, decrease or loss of touch or other senses
- dry mouth, increased sweating, feeling or being sick, diarrhoea or loose bowel motions, constipation, indigestion, stomach pain
- tiredness, sleepiness, sleeping difficulties
- weight increase or decrease
- sexual problems, painful erection
- frightening dreams, yawning, teeth grinding, increased or decreased appetite, impaired concentration
- excessive and/or abnormal movements
- increased muscle tension, muscle twitching

- vision disturbance, dilated pupils or eye pain
- menstrual irregularities, unusual vaginal bleeding
- loss of bladder control
- unusual hair loss or thinning
- 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
- mild rash, itchy skin
- ringing or other persistent noise in the ears
- migraine

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

- agitation, nervousness, anxiety, worsening of depression
- abnormal or suspicious thinking
- general swelling or swollen hands, ankles, feet or face or eye area due to fluid build-up
- severe stomach or abdominal pain
- symptoms of hyperglycaemia (high blood sugar): feeling hungry, thirsty and/or frequent or excessive urination
- agitation, anxiety, dizziness, feeling tense and restless, tired, drowsy, lack of energy, irritable, problems sleeping, headache, nausea and tingling or numbness of the hands and feet after stopping sertraline.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and are usually very rare. You may need urgent medical attention or hospitalisation.

- Convulsions (fits or seizures)
- coma (unconsciousness)
- a collection of symptoms including weight gain (despite loss of appetite), feeling and being sick, muscle weakness and irritability
- severe rash, with blisters and/ or excessive peeling of skin
- skin rash combined with inflamed blood vessels
- a sudden increase in body temperature, very high blood pressure, rigid muscles, nausea/vomiting and/or fits (convulsions). These symptoms may be signs of a rare condition called Serotonin Syndrome.
- Neuroleptic Malignant Syndrome (a serious reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions)
- fast, slow or irregular heartbeat, high blood pressure
- palpitations, fainting 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
- mood of excitement, over-activity and uninhibited behaviour or aggression
- hearing, seeing or feeling things that are not there (hallucinations)

- thoughts of suicide or attempting suicide or self-harm
- breathing problems
- jaundice (yellowing of the skin and/or eyes), with or without other signs of hepatitis or liver failure (loss of appetite, tiredness, feeling or being sick, dark urine, stomach pain or swelling, confusion, unconsciousness).

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to sertraline, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing.
- swelling of the face, lips, tongue, or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Sertraline looks like

50 mg tablets:

White to off white, capsule shaped, biconvex, film coated tablets with breakline on one side and '50' and 'BL' embossed on either side of the breakline.

100 mg tablets:

White to off white, capsule shaped, biconvex, film coated tablets with '100' and 'BL' embossed on one side.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 50 mg or 100 mg of sertraline as the active ingredient.

It also contains the following inactive ingredients:

- Calcium hydrogen phosphate anhydrous
- cellulose - microcrystalline
- hypromellose
- Sodium starch glycollate type A

- Magnesium stearate
- Hypromellose
- Titanium dioxide
- Macrogol 400
- Polysorbate 80

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Sertraline 50 mg tablets:

PVC/Al Blister packs of 30

AUST R 213177.

APO-Sertraline 100 mg tablets:

PVC/Al Blister packs of 30

AUST R 213180.

Sponsor

Apotex Pty Ltd

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