

APO-Sertraline Tablets

Sertraline (as sertraline hydrochloride)

Consumer Medicine Information

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

What is in this leaflet

This leaflet answers some common questions about this medicine. 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 this medicine against the benefits they expect it will 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 this medicine is used for

Sertraline is used to treat:

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

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 that 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, loss of sex drive and lack of energy.

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

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

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

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

There is not enough information to recommend the use of this medicine for depression in children under the age of 18 years.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing sertraline
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- 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

Do not take sertraline if you have epilepsy not properly controlled by medication.

Do not take this medicine if you are pregnant, plan to become pregnant or are breastfeeding.

Do not take this medicine if you are taking pimozone, used to treat disorders which affect the way you think, feel or act.

Do not take this medicine if you are taking a medicine known as a Monoamine Oxidase Inhibitors (MAOIs) or have been taking it within the last 14 days.

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 or vomiting and/or fits (convulsions). Do not take sertraline until 14 days after stopping any MAOI, and do not take MAOIs until 14 days after stopping sertraline.

Do not take this medicine if you are taking phentermine (a weight loss medicine), tryptophan (contained in protein-based foods or dietary supplements), methadone (used to treat pain or drug addiction), triptans

(medicines used to treat migraine), dextromethorphan (used as a cough suppressant in cold and flu medicines), and medicines used for pain management (such as fentanyl, tapentadol, tramadol, and pethidine).

These medicines can cause an exaggerated response to sertraline.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions:

- any mental illness (such as mania, hypomania or bipolar disorder)
- 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 causing irregular heartbeats
- liver problems
- kidney problems
- problems with blood clotting or abnormal bleeding
- diabetes mellitus
- glaucoma (an eye condition)
- thoughts or actions relating to self-harm or suicide

Tell your doctor if you are pregnant or plan to become pregnant.

Sertraline may affect your developing baby if you take it during pregnancy. There have been reports that babies exposed to sertraline and other antidepressants during the third trimester of pregnancy may develop complications after birth.

Your doctor will discuss with you the risks and benefits involved.

Tell your doctor if you are breast-feeding or you plan to breast-feed.

Sertraline passes into breast milk and may affect your baby. Your doctor will discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

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

Some medicines and sertraline may increase the risk of serious side effects and are potentially life-threatening. The following medicines must not be taken with sertraline:

- monoamine oxidase inhibitors (MAOIs), such as moclobemide, phenelzine, tranylcypromine, selegiline and linezolid
- pimozide, used to treat disorders which affect the way you think, feel or act

Some other medicines may interact with sertraline. These include:

- phentermine, a weight loss medicine
- tryptophan, contained in some protein-based foods and herbal preparations
- medicines for strong pain management such as fentanyl, tapentadol, tramadol or pethidine
- triptans, used for treating migraines e.g. sumatriptan, naratriptan and zolmitriptan
- St John's Wort (Hypericum perforatum), a herbal remedy for mood disorders
- other SSRIs e.g. fluoxetine, citalopram, paroxetine and fluvoxamine
- other medicines for depression, mood disorders or social anxiety

disorder e.g. dothiepin, desipramine, amitriptyline, lithium and venlafaxine

- dextromethorphan, used in cold and flu medicines to suppress cough
- 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 known to prolong bleeding, such as aspirin, other non-steroidal anti-inflammatory drugs (NSAIDs) and anti-coagulants (such as warfarin)
- cimetidine, used to treat stomach ulcers or reflux
- methadone, used to treat drug addiction
- diazepam, used to treat anxiety disorders
- medicines called diuretics, used to get rid of excess fluid from the body, and to treat high blood pressure
- dexamphetamine and lisdexamphetamine, medicines used to treat Attention Deficit Hyperactivity Disorder (ADHD)
- some antibiotics

These medicines may be affected by sertraline or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Other medicines not listed above may also interact with sertraline.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained within this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

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.

Depression

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

Social Phobia (Social Anxiety Disorder)

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

The maximum recommended dose is 200 mg per day.

Pre-Menstrual Dysphoric Disorder (PMDD)

The usual starting dose 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).

How to take it

Swallow the tablets with a full glass of water.

When to take it

Take your medicine at about the same time each day in the morning.

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

It does not matter if you take this medicine before 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.

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, 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.

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

If you forget to take it

If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

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)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia) for advice or go to Accident and Emergency Department at your nearest hospital, if you think that 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.

If you take too much sertraline, you may experience sedation, nausea, diarrhoea, vomiting, fast heartbeat, tremor, agitation, dizziness and unconsciousness.

While you are taking this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking sertraline.

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

If you become pregnant while taking this medicine, tell your doctor immediately. If you are a woman of child-bearing age, you should avoid becoming pregnant while taking sertraline.

When taken during pregnancy, particularly in the last 3 months of pregnancy, 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.

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

Depressive symptoms, including thoughts of suicide or self-harm, may worsen during the first one to two months of taking sertraline or after your dose changes. These symptoms should stop when the full effect of sertraline takes place.

This is more likely to occur if you are a young adult under 24 years of age, and you have not used antidepressant medicines before.

If you or someone you know demonstrates any of the following warning signs of suicide-related behaviour while taking sertraline, contact a doctor or mental health professional immediately:

- thoughts or talk of death or suicide
- thoughts or 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

All mentions of suicide or violence must be taken seriously.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you are about to have any urine or blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will monitor you to make sure the medicine is working and to prevent side effects.

Tell your doctor if you get a headache or start to feel dizzy, confused, forgetful, weak, unsteady or unable to concentrate.

Some people (especially older people or those taking diuretics/water tablets) may experience a lack of

sodium in the blood when taking this medicine.

Things you must not do

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

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

Your doctor may decide that you should continue to take it for some time, even when you have overcome your problem. For the 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, 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.

Things to be careful of

Be careful 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 other medicines for depression or MAOIs.

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.

Side effects

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

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- feeling tired and weak (fatigued), hot flushes, fever, feeling unwell, shaking or tremors, headache or dizziness
- muscle pain, stiffness, weakness or cramps, decrease or loss of touch or other senses
- dry mouth, increased sweating, feeling of being sick, diarrhoea or loose bowel motions,

- constipation, indigestion or stomach pain
- tiredness, sleepiness or sleeping difficulties
- weight increase or decrease
- increase or decrease appetite
- sleeping difficulties, sexual problems or painful erection
- sexual dysfunction (including impaired sexual function in males) that may continue even after stopping sertraline
- frightening dreams, yawning, teeth grinding, increased or decreased appetite
- impaired concentration
- excessive and/or abnormal movements
- increased muscle tension or 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 unusual secretion of breast milk in men or women
- increased sensitivity of the skin to sun
- mild rash or itchy skin
- ringing or other persistent noise in the ears
- migraine
- inflammation of the colon (causing diarrhoea)

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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

- headache, dizzy, confused, forgetful, weak, unsteady or unable to concentrate (may be a sign of reduced sodium in the blood)
- agitation, nervousness, anxiety or 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) such as feeling hungry, thirsty and/or frequent or excessive urination
- uncontrollable muscle spasms affecting the eyes, head, neck and body, temporary paralysis or weakness of muscles
- lockjaw
- painful or swollen joints
- uncontrollable movements of the body, shuffling walk or unusual weakness
- 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 any of the following happens, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital:

- 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, or 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)
- symptoms of an allergic reaction including 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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

Some of these side effects, such as changes to your blood count, can only be found when your doctor does tests from time to time to check your progress.

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 tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Ingredients

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

It also contains the following:

- Calcium hydrogen phosphate
- Microcrystalline cellulose
- Hypromellose
- Sodium starch glycolate type A
- Magnesium stearate
- Hypromellose
- Titanium dioxide
- Macrogol 400
- Polysorbate 80

This medicine does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Sponsor

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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' debossed on either side of the breakline. AUST R 213177.

Blister packs of 30.

100 mg tablets:

White to off white, capsule shaped, biconvex, film coated tablets with '100' and 'BL' debossed on one side. AUST R 213180.

Blister packs of 30.

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