

# SERTRALINE GENERICHEALTH

(sertraline hydrochloride) film-coated tablet

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Sertraline generichealth.

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 Sertraline generichealth 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 Sertraline generichealth is used for

Sertraline generichealth 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.

Sertraline generichealth 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 Sertraline generichealth for another purpose.

**Ask your doctor if you have any questions about why Sertraline generichealth has been prescribed for you.**

Sertraline generichealth should not be used in children and adolescents under the age of 18 years for the treatment of any medical condition other than obsessive compulsive disorder (OCD). The safety and efficacy of Sertraline generichealth for the treatment of medical conditions (other than OCD) in this age group has not been satisfactorily established.

For the treatment of OCD, Sertraline generichealth is not recommended for use in children under the age of 6, as the safety and efficacy in children of this age group has not been established.

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

There is no evidence that sertraline tablets are addictive.

### Before you take Sertraline generichealth

#### When you must not take it

**Do not take Sertraline generichealth 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 or other parts of the body;
- rash, itching or hives on the skin.

**Do not take Sertraline generichealth if you have epilepsy not properly controlled by medication.**

**Do not take Sertraline generichealth if you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking it within the last 14 days.**

Taking Sertraline generichealth with a MAOI (eg. Aurorix, Eldepryl, Nardil and Parnate) may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and convulsions (fits).

**Do not take Sertraline generichealth if you are taking:**

- phentermine (used to help weight loss);
- tryptophan (contained in protein-based foods or dietary proteins);
- methadone (used to treat drug addiction);
- medicines used to treat migraine, eg. sumatriptan (Imigran);
- dextromethorphan (used as a cough suppressant in cold and flu medication);
- medicines used for pain management such as fentanyl, tapentadol (Palexia), tramadol or pethidine.

These medicines can cause an exaggerated response to Sertraline generichealth.

**Do not take Sertraline generichealth if you are taking pimozide (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 Sertraline generichealth to children or adolescents under the age of 18 unless the doctor has prescribed it for the treatment of OCD. Do not give Sertraline generichealth to children under the age of 6 for the treatment of OCD.**

**If you are not sure whether you should be taking Sertraline generichealth, talk to your doctor.**

**Do not take Sertraline generichealth 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 it has expired or is damaged, return it to your pharmacist for disposal.**

*Before you start to take it*

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

**Tell your doctor if you have or have had any of the following medical conditions:**

- any other mental illness;
- epilepsy or seizures;

- liver or kidney problems;
- heart conditions causing irregular heartbeats;
- a tendency to bleed more than normal;
- diabetes mellitus;
- glaucoma, an eye condition.

**Tell your doctor if you are pregnant or intend to become pregnant.** There have been reports that babies exposed to sertraline tablets and other antidepressants during the third trimester of pregnancy may develop complications immediately after birth.

If you take Sertraline generichealth near the end of your pregnancy, there may be an increased risk of heavy vaginal bleeding shortly after birth (postpartum haemorrhage).

**Tell your doctor if you are breastfeeding or wish to breastfeed.** Sertraline generichealth passes into breast milk and may affect your baby.

Your doctor will discuss the risks and benefits of taking Sertraline generichealth when pregnant or breastfeeding.

#### Taking other medicines

**Tell your doctor or pharmacist if you are taking any other medicines, including:**

- all prescription medicines;
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by Sertraline generichealth or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

**Tell your doctor or pharmacist if you are taking any of the following:**

- other medicines for the treatment of depression called monoamine oxidase inhibitors (MAOIs). Taking Sertraline generichealth 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;
- other MAOI drugs such as linezolid, an antibiotic used to treat pneumonia and certain skin infections;
- other medicines for depression, panic disorder, social anxiety disorder or obsessive illnesses (eg. Prothiaden, Prozac, Aropax, Luvox, Cipramil, Efexor XR, Xydep);
- lithium (eg. Lithicarb), a medicine used to treat mood swings;
- other medicines for PMDD (eg. Prozac, Lovan, Xydep);
- tryptophan (contained in protein-based foods or dietary proteins);
- phentermine (weight-reducing medicines);
- dextromethorphan (used in cold and flu medicines to suppress cough);
- medicines for strong pain management such as fentanyl, tapentadol (Palexia), tramadol or pethidine;

- methadone (used to treat drug addiction);
- other medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis (eg. aspirin or NSAIDs such as ibuprofen or diclofenac);
- pimozone (used to treat disturbances in thinking, feeling and behaviour);
- St John's Wort, a herbal remedy used to treat mood disorders;
- medicines for treating psychotic illness such as clozapine, (eg. Clozaril) which is used to treat schizophrenia;
- medicines for irregular heartbeats (eg. Tambocor);
- warfarin (eg. Marevan, Coumadin) or other medicines that stop the blood from clotting;
- phenytoin (eg. Dilantin), a medicine used to treat epilepsy;
- metamizole (used for pain relief)
- sumatriptan (eg. Imigran), a medicine used to treat migraine;
- diazepam or other medicines that act on the brain or nervous system (eg. Serepax, Valium);
- cimetidine (eg. Tagamet), a medicine used to treat reflux and ulcers;
- medicine used to treat Attention Deficit Hyperactivity Disorder (ADHD) such as dexamphetamine and lisdexamphetamine;
- antibiotics.

Not all brand names are given for the medicines listed above. Your doctor or pharmacist has more information on these medicines or other medicines to be careful with or avoid while taking Sertraline generichealth.

**If you have not told your doctor or pharmacist about these things, tell them before you start taking Sertraline generichealth.**

Some combinations of medicines may increase the risk of serious side effects and are potentially life-threatening.

## How to take Sertraline generichealth

**Follow all directions given to you by your doctor.**

They may differ from the information contained in this leaflet.

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

Sertraline generichealth is available in 50 mg and 100 mg strengths. If your doctor has prescribed a dose such as 25 mg or 75 mg, please note that Sertraline generichealth 50 mg tablets have a scoreline and can be broken in half to allow such doses to be taken.

### How much to take

Your doctor will tell you how many tablets you need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines.

### Depression - Adults

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.

### Obsessive Compulsive Disorder - Children (6-12 Years)

The usual starting dose is 25 mg a day which is half a 50 mg tablet. Increase to one 50 mg tablet a day after one week.

### Obsessive Compulsive Disorder - Adults and Adolescents (13-18 Years)

The usual starting dose is one 50 mg tablet each day

### Panic Disorder - Adults

The usual starting dose is 25 mg a day which is half a 50 mg tablet. Increase to one 50 mg tablet a day after one week.

### Social Phobia (Social Anxiety Disorder) - Adults

The usual starting dose is 25 mg a day which is half a 50 mg tablet. Increase to one 50 mg a day after one week.

**Do not take more than 200 mg a day for the conditions listed above.**

### Premenstrual Dysphoric Disorder (PMDD)

**If taking throughout the menstrual cycle**

The usual starting dose is one 50 mg tablet a day. This may be increased to a maximum of 150 mg a day if needed. Increase the dose in a step wise fashion. If you are unclear how to do this ask your pharmacist or doctor for advice.

**If taking in the last 14 days of the menstrual cycle**

The usual starting dose is one 50 mg tablet a day. This may be increased to a maximum of 100 mg a day.

**Do not take more than the maximum doses recommended above for PMDD.**

### How to take it

**Swallow the tablets with a glass of water.**

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

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

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 Sertraline generichealth.

**Continue taking Sertraline generichealth until your doctor tells you to stop.**

Even when you feel well, you may need to take Sertraline generichealth for several months or longer.

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

**Do not stop taking Sertraline generichealth, or change the dose, without first checking with your doctor.**

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 (ie. 1 to 2 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.**

**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*

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

Wait until the next day and take your normal dose then.

**If you are not sure what to do in this situation, ask your doctor or pharmacist.**

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

*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 at your nearest hospital if you think you or anyone else may have taken too much Sertraline generichealth.**

**Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

Symptoms of an overdose may include:

- feeling drowsy
- nausea, diarrhoea, vomiting
- fast or irregular heartbeats
- tremors
- feeling agitated or dizzy.

## While you are taking Sertraline generichealth

### Things you must do

**Tell all doctors, dentists and pharmacists who are treating you that you are taking Sertraline generichealth.**

**Tell your doctor or pharmacist that you are taking Sertraline generichealth if you are about to be started on any new medicines.**

**Tell your doctor if you become pregnant while taking Sertraline generichealth.**

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

**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 Sertraline generichealth or when the doctor changes your dose. These symptoms should be subsided when the full effect of Sertraline generichealth 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.

Patients and caregivers should be alert and monitor for these effects.

**Signs and symptoms of suicide include:**

- 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 mention of suicide or violence must be taken seriously.**

**If you or someone you know is demonstrating these warning signs of suicide while taking Sertraline generichealth, contact your doctor or a mental health professional right away.**

**Children should have regular check-ups with the doctor to monitor growth and development.**

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

It may interact with other medicines used during surgery and cause unwanted side effects.

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

It may interfere with the results of some tests.

*Things you must not do*

**Do not stop taking Sertraline generichealth, 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 Sertraline generichealth may cause dizziness, light-headedness, 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 Sertraline generichealth 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 Sertraline generichealth 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 Sertraline generichealth, your doctor may suggest avoiding alcohol while you are taking Sertraline generichealth.

**If you are feeling drowsy or are uncoordinated, be careful that you do not fall over.**

Sertraline generichealth, like other medicines in this class, may increase your risk of bone fracture.

**You should wait at least 14 days after stopping Sertraline generichealth before starting any other 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 Sertraline generichealth.

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

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## Side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

It can be difficult to tell whether side effects are the result of taking Sertraline generichealth, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

**Do not be alarmed by the list 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 if...*

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

- headache, dizziness, shaking or tremors, unusually overactive, muscle stiffness or weakness, decrease or loss of touch or other senses, sleepiness, drowsiness, impaired concentration;
- dry mouth, nausea, feeling sick, diarrhoea, indigestion, vomiting, stomach pain, constipation;
- increased sweating, rash and hives;
- tiredness, fever, feeling unwell;
- hot flush, high blood pressure;
- weight increase or loss;
- increased or decreased appetite;
- sleeping difficulties, sexual problems;
- vision disturbance;
- menstrual irregularities, sexual dysfunction including impaired sexual function in males, difficulty in passing urine, or increased frequency;
- persistent noise in the ears
- tingling and numbness of hands and feet;
- inflammation of the colon (causing diarrhoea).

*Tell your doctor as soon as possible if...*

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

- agitation, nervousness, anxiety, frightening dreams, yawning, abnormal thinking, teeth grinding, symptoms of agitation, anxiety dizziness, headache, nausea and tingling or numbness of the hands and feet after stopping Sertraline generichealth;
- uncontrollable muscle spasms affecting the eyes, head, neck and body, temporary paralysis or weakness of muscles;
- lockjaw;
- painful, swollen joints;
- difficulty in breathing, wheezing or coughing;
- uncontrollable movements of the body, shuffling walk, unusual weakness;
- palpitations, fainting or chest pain;
- irregular heartbeats;
- abnormal bleeding including vaginal bleeding;

- sudden onset of severe headache.

*Go to hospital if...*

**Tell your doctor immediately, or go to Accident and Emergency at 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 heartbeat and muscle stiffness, which may lead to loss of consciousness;
- thoughts of suicide or attempting suicide or self-harm.

The following symptoms are signs of side effects named Serotonin Syndrome (SS) or Neuroleptic Malignant Syndrome (NMS). SS is caused by medications which build up high levels of serotonin in the body. NMS is a life threatening emergency associated with the use of antipsychotic medicines. The risk of SS and NMS with SSRI's is increased with combined use of other SSRIs, MAOIs and other antipsychotic medicines.

- agitation
- hallucinations
- coma
- fast heart beat
- fluctuating blood pressure readings
- high body temperature
- twitching and spastic body movements
- lack of body co-ordination
- nausea
- vomiting
- diarrhoea

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

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

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

Some of these side effects (eg. changes in thyroid function, liver function or glucose control) can only be found when your doctor does tests from time to time to check your progress.

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## After taking Sertraline generichealth

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### Storage

**Keep your tablets where young children cannot reach them.**

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

**Keep Sertraline generichealth in a cool, dry place where the temperature stays below 30 C. 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 Sertraline generichealth or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.**

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## Product description

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### *What it looks like*

Sertraline generichealth 50 mg tablets are blue coloured, capsule shaped, biconvex, film coated tablets debossed with “SER” on one side and “5” and “0” on either side of the breakline on the other side.

Sertraline generichealth 100 mg tablets are yellow coloured, capsule shaped, biconvex, film coated tablets debossed with “SER” on one side and “100” on the other side.

A carton contains 30 tablets.

### *Ingredients*

#### *Active ingredient*

Each Sertraline generichealth tablet contains 50 mg or 100 mg sertraline (as hydrochloride).

#### *Other ingredients*

- microcrystalline cellulose;
- calcium hydrogen phosphate;
- hypromellose;
- sodium starch glycolate;
- magnesium stearate;
- Opadry complete film coating system 13B50666 blue (50 mg strength);
- Opadry complete film coating system 13B52105 yellow (100 mg strength).

### *Australian Registration Numbers*

Sertraline generichealth 50 mg: AUST R 124855.

Sertraline generichealth 100 mg: AUST R 124856.

### *Sponsor*

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