

SERTRALINE GENERICHEALTH

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 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.

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 not to take it

Do not take Sertraline generichealth if:

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

Some of the symptoms of an allergic reaction to sertraline tablets may include a skin rash, itchiness, difficulty breathing and swelling of the face.

- 2. you have epilepsy not properly controlled by medication.**
- 3. 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).

- 4. 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 Sertraline generichealth.

- 5. you are taking pimozide (used to treat disturbances in thinking, feeling and behavior).**

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. 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 tampering.

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

Before you start to take it

Tell your doctor if:

- 1. You are allergic to any foods, dyes, preservatives or any other medicines.**

2. You have any health problems, including:

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

3. You are pregnant or intend to become pregnant.

The effects of Sertraline generichealth on the developing baby are not yet known. There have been reports that babies exposed to sertraline tablets and other antidepressants during the third trimester of pregnancy may develop complications after birth.

4. 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 using Sertraline generichealth 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 Sertraline generichealth.

These include:

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

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

You may respond differently to Sertraline generichealth, 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, 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 Sertraline generichealth.

If you have not told your doctor or pharmacist about these things,

tell them before you start taking Sertraline generichealth.

How to take Sertraline generichealth

Take Sertraline generichealth 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.

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

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

For PREMENSTRUAL DYSPHORIC DISORDER the usual starting dose for Sertraline generichealth 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.

Sertraline generichealth can be taken with or without food.

How long to take it for

Most medicines for depression 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.

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

Continue taking Sertraline generichealth 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 Sertraline generichealth, or change the dose, without first checking with your doctor.

If you take too much

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 Sertraline generichealth, 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 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 controlled when the full effect of Sertraline generichealth takes place.

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 self harm
- increase in aggressive behaviour, irritability or agitation
- worsening of depression

Mentions 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.

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.

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, 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 Sertraline generichealth to treat any other complaints unless your doctor says so.

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.

You should wait at least 14 days after stopping Sertraline generichealth 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 Sertraline generichealth. The effects of Sertraline generichealth 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 Sertraline generichealth, even if you do not think the problems are connected with the medicine or the problems are not listed in this leaflet.

Like other medicines, Sertraline generichealth 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 Sertraline generichealth.

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, diarrhea, 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 disturbances
- 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
- increase 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. Other 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.

How to store Sertraline generichealth

Storage

Keep your tablets where young children cannot reach them.

A locked cupboard at least 1 ½ 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 degrees Celsius. Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or 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.

Product description

What Sertraline generichealth tablets look like

Sertraline generichealth comes in two strengths:

Sertraline generichealth 50 mg 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 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 ingredients

Sertraline generichealth 50 mg
contains 50 mg sertraline (as
hydrochloride) per tablet

Sertraline generichealth 100 mg
contains 100 mg sertraline (as
hydrochloride) per tablet.

Other ingredients

- microcrystalline cellulose
- anhydrous calcium hydrogen phosphate
- hydroxypropyl cellulose
- sodium starch glycolate magnesium
- stearate
- opadry blue
- opadry yellow

Sertraline generichealth does not
contain gluten or sugar.

Sponsor

Generic Health Pty Ltd
Level 1, 1102 Toorak Road
Camberwell VIC 3124
Australia

***Australian Registration
Number***

Sertraline generichealth 50 mg -
AUST R 124855

Sertraline generichealth 100 mg -
AUST R 124856

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