

SERTRALINE-TIH TABLETS

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using SERTRALINE-TIH?

SERTRALINE-TIH contains the active ingredient sertraline hydrochloride. SERTRALINE-TIH is used to treat obsessive compulsive disorder (OCD) in children over the age of 6 and depression, OCD, panic disorder, social anxiety disorder and pre-menstrual dysphoric disorder (PMDD) in adults. For more information, see Section [1. Why am I using SERTRALINE-TIH?](#) in the full CMI.

2. What should I know before I use SERTRALINE-TIH?

Do not use if you have ever had an allergic reaction to sertraline or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use SERTRALINE-TIH?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SERTRALINE-TIH and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use SERTRALINE-TIH?

Obsessive Compulsive Disorder	Starting dose is 25 mg a day (half a 50 mg tablet) for children and 50 mg tablet per day for adults and adolescents.
Depression	Starting dose is one 50 mg tablet per day.
Panic disorder and Social Phobia	Starting dose is 25 mg per day (half a 50 mg tablet).
PMDD	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).

More instructions can be found in Section [4. How do I use SERTRALINE-TIH?](#) in the full CMI.

5. What should I know while using SERTRALINE-TIH?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using SERTRALINE-TIH.• If you become pregnant while taking this medicine, tell your doctor immediately.• Call your doctor straight away if you have any suicidal thoughts or other mental/mood changes.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not take sertraline if you are taking any other medicines for depression or monoamine oxidase inhibitors (MAOIs) or have been taking them within the last 14 days.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how sertraline affects you.• This medicine may cause dizziness, drowsiness or impaired concentration in some people.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine below 25°C• Keep your medicine in its original packaging until it is time to take it.

For more information, see Section [5. What should I know while using SERTRALINE-TIH?](#) in the full CMI.

6. Are there any side effects?

Some of the very serious side effects include convulsions, coma, breathing problems, a sudden increase in body temperature, very high blood pressure, hallucinations, thoughts of suicide. You may need urgent medical attention or hospitalization.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CM

SERTRALINE-TIH TABLETS

Active ingredient(s): *Sertraline (as sertraline hydrochloride)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using sertraline hydrochloride. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using sertraline hydrochloride.**

Where to find information in this leaflet:

- [1. Why am I using SERTRALINE-TIH?](#)
- [2. What should I know before I use SERTRALINE-TIH?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use SERTRALINE-TIH?](#)
- [5. What should I know while using SERTRALINE-TIH?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using SERTRALINE-TIH?

SERTRALINE-TIH contains the active ingredient sertraline hydrochloride. SERTRALINE-TIH 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.

SERTRALINE-TIH is used to treat:

- depression
- obsessive compulsive disorder (OCD)
- panic disorder
- 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.

This medicine 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 this medicine for the treatment of medical conditions (other than OCD) in this age group has not been satisfactorily established.

For the treatment of OCD, this medicine 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.

2. What should I know before I use SERTRALINE-TIH?

Warnings

Do not use SERTRALINE-TIH if:

- You are allergic to sertraline hydrochloride, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- You have epilepsy not properly controlled by medication.
- You are pregnant, plan to become pregnant or are breastfeeding
- You are taking pimozide, used to treat disorders which affect the way you think, feel or act.
- 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.
- 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 pentidine). These medicines can cause an exaggerated response to sertraline.
- It has expired or if the packaging is torn or shows signs of tampering.

Do not give SERTRALINE-TIH:

- To children or adolescents under the age of 18 unless the doctor has prescribed it for the treatment of OCD.

- To children under the age of 6 for the treatment of OCD.

Check with your doctor if you have or have had any of the following 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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend 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 immediately after birth e.g. you may experience heavy vaginal bleeding shortly after birth (postpartum haemorrhage). Your doctor will discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

3. What if I am taking other medicines?

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

Some medicines may interfere with SERTRALINE-TIH and affect how it works.

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

- monoamine oxidase inhibitors (MAOIs), such as moclobemide, phenelzine, tranylcypromine, selegiline and linezolid

- pimozone, used to treat disorders which affect the way you think, feel or act.

The following 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.

- 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

Other medicines not listed above may also interact with sertraline.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SERTRALINE-TIH.

4. How do I use SERTRALINE-TIH?

How much to take

- **Depression in 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 in 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.

- **Adults and Adolescents (13-18 Years)**

The usual starting dose is one 50 mg tablet each day.

- **Panic Disorder in adults**

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

- **Social Phobia (Social Anxiety Disorder) in adults**

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

- **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).

Follow the instructions provided and use SERTRALINE-TIH until your doctor tells you to stop.

When to take

- Take SERTRALINE-TIH at about the same time each day in the morning.
It does not matter if you take this medicine before or after food.

How to take

- Swallow the tablets with a full glass of water.

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 antidepressant 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 SERTRALINE-TIH

SERTRALINE-TIH should be used regularly at the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

If you miss your dose at the usual time, if it is almost time for 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 you missed.

This may increase the chance of you experiencing side effects.

If you use too much SERTRALINE-TIH

If you think that you have used too much SERTRALINE-TIH, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should 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.

5. What should I know while using SERTRALINE-TIH?

Things you should do

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.

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.

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

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.

Call your doctor straight away 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.
- You or someone you know demonstrates any of the following warning signs of suicide-related behaviour while taking sertraline:
 - 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.

Remind any doctor, dentist or pharmacist you visit that you are using SERTRALINE-TIH.

Things you should 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.

- 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. 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SERTRALINE-TIH 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may worsen the dizziness, drowsiness, or impaired concentration.

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.

Looking after your medicine

- 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 below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> 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 	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> ringing or other persistent noise in the ears migraine inflammation of the colon (causing diarrhoea). 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> 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 difficulty in breathing, wheezing or coughing palpitations, fainting or chest pain irregular heartbeats abnormal bleeding including vaginal bleeding sudden onset of severe headache rapid onset of shortness of breath, cough, fatigue, night sweats and weight loss. 	<p>Tell your doctor as soon as possible if you notice any of these serious side effects.</p>

Very serious side effects

Very serious side effects	What to do

<ul style="list-style-type: none"> • 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* (SS). SS is caused by medications which build up high levels of serotonin in the body. • Neuroleptic Malignant Syndrome* (NMS) – a serious reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions. NMS is a life threatening emergency associated with the use of antipsychotic medicines. • lack of body co-ordination • nausea, vomiting, diarrhea • 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, 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p>
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<ul style="list-style-type: none"> • 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 	
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*The risk of SS and NMS with SSRI's is increased with combined use of other SSRIs, MAOIs and other antipsychotic medicines.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What SERTRALINE-TIH contains

Active ingredient (main ingredient)	Sertraline hydrochloride 50 mg or 100 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • Calcium hydrogen phosphate • Microcrystalline cellulose • Hyprollose • Sodium starch glycollate type A • Magnesium stearate • Hypromellose • Titanium dioxide • Macrogol 400 • Polysorbate 80

Do not take this medicine if you are allergic to any of these ingredients.

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

What SERTRALINE-TIH 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 213178).

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 213181).

Blister packs of 30.

Who distributes SERTRALINE-TIH

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

Australia

Tel: +61 2 8877 8333

Web: www.apotex.com/au

This leaflet was prepared in January 2024.