

# SETRONA

## 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 SETRONA?

SETRONA contains the active ingredient sertraline hydrochloride. SETRONA is used to treat depression and conditions called obsessive compulsive disorder (OCD), panic disorder, social phobia (social anxiety disorder) and premenstrual dysphoric disorder (PMDD).

For more information, see Section [1. Why am I using SETRONA?](#) in the full CMI.

### 2. What should I know before I use SETRONA?

Do not use if you have ever had an allergic reaction to SETRONA 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 SETRONA?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with SETRONA 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 SETRONA?

- SETRONA is to be taken by mouth, every morning or evening with or without food. Swallow the tablet whole with a full glass of water.
- Take SETRONA exactly as your doctor has prescribed.

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

### 5. What should I know while using SETRONA?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using SETRONA.</li><li>• Take SETRONA exactly as your doctor tells you to.</li><li>• Visit your doctor regularly for check ups.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not give this medicine to anyone else, even if they have the same condition as you.</li><li>• Do not use SETRONA tablets to treat any other complaints unless your doctor tells you to.</li><li>• Do not stop taking SETRONA tablets, or lower the dose, without first checking with your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how SETRONA affects you.</li><li>• SETRONA tablets may affect your ability to drive a car or operate machinery.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li><li>• Although drinking moderate amounts of alcohol is unlikely to affect your response to SETRONA, your doctor may suggest avoiding alcohol while you are taking SETRONA.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your SETRONA in a cool, dry place where it stays below 25°C.</li></ul>

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

### 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.

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

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

# SETRONA

Active ingredient(s): *sertraline hydrochloride*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using SETRONA. **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 SETRONA.**

Where to find information in this leaflet:

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

## 1. Why am I using SETRONA?

**SETRONA contains the active ingredient sertraline hydrochloride.** SETRONA belongs to a group of medicines known as selective serotonin reuptake inhibitors (SSRIs). These medicines are thought to work by increasing the activity of the chemical serotonin in the brain.

**SETRONA is used to treat depression and conditions called obsessive compulsive disorder (OCD), panic disorder, social phobia (social anxiety disorder) and premenstrual 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. This imbalance affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, being unable to enjoy life, poor appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty over nothing. SETRONA corrects this chemical imbalance and may help relieve the symptoms of depression.

PMDD affects women in the days before their period. PMDD is different from pre-menstrual 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.

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.

Your doctor, however, may have prescribed SETRONA for another purpose. Ask your doctor if you have any questions about why SETRONA tablets have been prescribed for you.

SETRONA is only available with a doctor's prescription. There is no evidence that SETRONA is addictive.

## 2. What should I know before I use SETRONA?

### Warnings

**Do not use SETRONA 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 SETRONA with a MAOI (eg seligeline, phenelzine, tranylcypromine, moclobemide) may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and convulsions (fits).
- You have epilepsy not properly controlled by medication
- You are pregnant, plan to become pregnant or are breastfeeding
- You are taking pimozide (medicines used for treating mental illness).
- 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 penthidine). These medicines can cause an exaggerated response to sertraline
- You are allergic to sertraline, or any of the ingredients listed at the end of this leaflet.
- Some of the symptoms of an allergic reaction to SETRONA may include a skin rash, itchiness, difficulty breathing and swelling of the face.
- Always check the ingredients to make sure you can use this medicine.
- Do not take **SETRONA** tablets after the expiry date printed on the pack. If you take it after the expiry date has passed, it may not work as well. Do not take **SETRONA** if the tablets do not look quite right.
- Do not take **SETRONA** tablets if the packaging is torn or shows signs of tampering.

**Do not give SETRONA:**

- 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 any other medical conditions especially the following:
  - Liver or kidney problems
  - History of a heart attack or have heart problems
  - Epilepsy or seizures
  - History of bleeding disorders or a tendency to bleed more than normal
  - Bipolar disorder (manic depression)
  - Syndrome of Inappropriate Antidiuretic Hormone Secretion
  - Mental illness, family history of suicide or depression
  - Pregnant or intend to become pregnant
- take any medicines for any other condition
- have any allergies to any other medicines and any other substances, such as foods, preservatives or dyes

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.

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

Your doctor will discuss the risk and benefits of taking SETRONA during pregnancy.

The effects of SETRONA on the developing baby are not known yet. However, there have been reports that babies exposed to SETRONA and other SSRIs antidepressants during the third trimester of pregnancy may develop complications after birth.

Make sure your doctor know you are on SETRONA. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like SETRONA 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 doctor immediately.

SETRONA passes into breast milk and may affect your baby. Side effects have been reported in babies exposed to sertraline during breastfeeding. Your doctor will discuss the risks and benefits of using SETRONA when breastfeeding.

## 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 should not be taken with SETRONA as it may increase the risk of serious side effects and are potentially life-threatening these include:**

- Medicines called monoamine oxidase inhibitors (MAOI) such as phenelzine (NARDIL), tranylcypromine (PARNATE), moclobemide (AURORIX) and selegiline (ELDEPRYL). Taking SETRONA with, or within fourteen 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 SETRONA such as tramadol (pain reliever), tryptophan (a complementary medicine), or phentermine (a weight reducing medicine) and sumatriptan (medicine used to relieve migraine attack).
- Pimozide (use to treat disturbances in thinking, feeling and behaviour).
- St John's wort, a herbal remedy.

**Some medicines may interfere with SETRONA and affect how it works.**

You may respond differently to SETRONA, or to some other medicines, if you take them together. These include:

- Phentermine, a weight loss medicine
- Tryptophan, contained in some protein-based foods and herbal preparations
- medicines for strong pain management (e.g. 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)
- Dextromethorphan, used in cold and flu medicines to suppress cough
- Medicines used to treat heart conditions (e.g. flecainide and propafenone)
- Other medicines for depression, panic disorders, social anxiety disorders or obsessive compulsive disorder.
- medicines for Pre-Menstrual Dysphoric Disorder (e.g. fluoxetine)
- medicine used to treat mental illnesses or mood disorders (e.g. clozapine, lithium)
- medicines for irregular heart beat (e.g. flecainide)
- medicines that can cause abnormal bleeding such as non-steroidal anti-inflammatory drugs (NSAIDs), aspirin, medicines that stop the blood from clotting like warfarin.
- phenytoin (e.g. Dilantin), a medicine used for epilepsy

- Diazepam or other medicines to treat sleeping disorders, anxiety or help to relax the muscles (e.g. Serepax, valium)
- Tolbutamide (eg Rastinon), a medicine used to treat diabetes
- Cimetidine (e.g. Tagamet), a medicines used to treat reflux and ulcers.
- Methadone, a medicine used to treat drug addiction
- Metamizole, an inducer of metabolising enzymes

These medicines may be affected by SETRONA tablets, or may affect how well it works. You may need to use different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist will be able to tell you what to do when taking/being given SETRONA tablets with other medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking SETRONA. If you have not told your doctor or pharmacist about these things, tell them before you start taking SETRONA.

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

## 4. How do I use SETRONA?

### How much to take / use

- SETRONA is to be taken by mouth, every morning or evening with or without food. Swallow the tablet whole with a full glass of water.
- Take SETRONA exactly as your doctor has prescribed.

#### For Major Depression in Adults

- The usual starting dose is one SETRONA 50 mg tablet taken once daily. It is possible that your doctor may decide to increase your daily doses, depending on your response to treatment. The maximum daily dose should not exceed 200 mg.

#### For Obsessive Compulsive Disorder in Children (6-12 years)

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

#### For Obsessive Compulsive Disorder in Adults and Adolescents (13-18 years)

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

#### For Panic Disorder in adults

- The usual starting dose for SETRONA is 25 mg per day, increasing to 50 mg per day after one week.

#### For social phobia (social anxiety disorder) in adults

- The usual starting dose for SETRONA is 25 mg per day, increasing to
- 50 mg per day after one week.
- The maximum recommended dose of SETRONA for the conditions listed above is 200 mg per day.

#### For Premenstrual Dysphoric Disorder

- The usual starting dose is one SETRONA 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 menses (to a maximum of 100 mg daily). However, depending on your condition and how you react to SETRONA, your doctor may ask you to take some other dose. The maximum recommended daily dose should not exceed 200 mg.
- Your dosage would be different if you have liver problems.
- Follow the instructions provided and use SETRONA until your doctor tells you to stop. Your doctor may need to regularly examine you to decide if it is necessary for you to continue taking or stop SETRONA tablets.

### When to take / use SETRONA

- Take your SETRONA tablets at about the same time each day. Taking your tablets at the same time each day will have the best effect. It will also help you to remember when to take the tablets.

### How long to take it

- Most medicines for depression and obsessive illness 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 SETRONA. 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 SETRONA for several months or even longer to make sure the benefits will last. Continue to take it 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 SETRONA, 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 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 use SETRONA

SETRONA should be used regularly at the same time each day.

**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, then go back to taking it as you would normally.

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

If you are not sure what to do, ask your doctor or pharmacist.

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

### **If you use too much SETRONA**

If you think that you have used too much SETRONA, 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.**

If you take too many SETRONA tablets, you may feel drowsy, sick in the stomach, have a fast heartbeat, have tremors, feel agitated or dizzy. Coma has also been reported with the overdose.

## **5. What should I know while using SETRONA?**

### **Things you should do**

Take SETRONA exactly as your doctor tells you to.

Try not to miss any doses and take the medicine even if you feel well.

Visit your doctor regularly for check ups.

Tell all doctors, dentists and pharmacists who are treating you that you are taking SETRONA.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking SETRONA.

If you plan to have surgery make sure you tell your doctor, dentist or anaesthetist that you are taking SETRONA.

If you become pregnant or intend to become pregnant while taking SETRONA, you should make an appointment to see your doctor and have your treatment reviewed. It is important that you do not stop taking SETRONA suddenly. SETRONA is a medicine that can have withdrawal side effects if stopped suddenly. Withdrawal symptoms (e.g. feeding difficulty, vomiting, tremor, irritability, unstable temperature) have also been reported rarely in the newborn baby after maternal use in the last 3 months of pregnancy.

If you take this medicine during late pregnancy, the newborn may be at increased risk of developing troubled breathing, bluish skin, fits, changes in body temperature, feeding difficulties, vomiting and cough (signs of persistent pulmonary hypertension).

Your doctor will discuss the risks and benefits of taking SETRONA during pregnancy.

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 SETRONA or when the doctor changes your dose. These symptoms should be controlled when the full effect of SETRONA takes place.

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 of talk of death or suicide, self-harm or harm to others
- Any recent attempts of self-harm
- Increase in aggressive behaviour, irritability or agitation
- Worsening of depression

All mentions of suicide or violence must be taken seriously.

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

Tell your doctor immediately if you develop symptoms and signs of serotonin syndrome.

**Signs and symptoms of serotonin syndrome include:**

- Incoordination
- Trembling, abrupt contraction of muscles
- Confusion
- Agitation
- Sweating
- Fever
- Shivering
- Diarrhoea.

**Tell your doctor if you develop symptoms and signs of hyponatraemia (decreased level of sodium in blood), such as:**

- Headache
- Difficulty in concentration
- Memory impairment
- Confusion
- Weakness
- Unsteadiness

In cases of sudden and/or severe hyponatraemia, symptoms such as hallucination (seeing, feeling or hearing things that are not there), fainting, seizure, coma, respiratory arrest, and death have also been reported.

Risk of developing hyponatraemia is greater if you:

- are elderly
- are on diuretics (fluid or water tablets)
- have Syndrome of Inappropriate Antidiuretic Hormone Secretion

## Things you should not do

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

Do not use SETRONA tablets to treat any other complaints unless your doctor tells you to.

Do not stop taking SETRONA tablets, or lower the dose, without first checking with your doctor.

Suddenly stopping SETRONA may cause dizziness, lightheadedness, numbness, feeling sick, unusual tingling feelings, shakiness or anxiety.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use SETRONA to treat any other complaints unless your doctor says to.

## Things to be careful of

If you are to switch to another medicine for depression from the MAOI group such as Aurox, Nardil or Parnate, you should wait at least 14 days after stopping SETRONA before starting the MAOI medicine.

All the above precautions are important even after you have stopped taking SETRONA. The effects of SETRONA may last for some days after you have stopped taking it.

## Driving or using machines

**Be careful before you drive or use any machines or tools until you know how SETRONA 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.

SETRONA tablets may affect your ability to drive a car or operate machinery.

SETRONA may cause dizziness in some people.

## Drinking alcohol

**Tell your doctor if you drink alcohol.**

Although drinking moderate amounts of alcohol is unlikely to affect your response to SETRONA, your doctor may suggest avoiding alcohol while you are taking SETRONA.

## Looking after your medicine

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the box or the blister pack they may not keep well.

Keep your SETRONA in a cool, dry place where it stays 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.

**Keep it where young children cannot reach it.**

## 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.

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"><li>• Nausea (feeling sick), vomiting (being sick), indigestion, loose stools (diarrhoea), dry mouth, abdominal pain, increased or decreased appetite, constipation</li><li>• Headache, dizziness, lack of sleep or drowsiness, excessive sweating, inability to concentrate, nervousness, yawning, teeth grinding</li><li>• Tingling and numbness in hands and feet</li><li>• Decreased sexual performance including failure of ejaculation in males, decreased or increased sexual desire, impotence, lack of orgasm in female patients</li><li>• Mental confusion or agitation, excessive excitement, hallucinations</li><li>• Increased tendency to bleed or abnormal bleeding, predominantly of the skin and mucous membranes (including nasal, vaginal and gastrointestinal bleeding).</li><li>• Urinary disturbances</li><li>• Puffiness of face, fever, blushing, weight loss or gain, vague feeling of being unwell</li><li>• Ringing in the ears</li><li>• Increased production of the hormone prolactin, which may result in abnormal production of breast milk or breast enlargement</li><li>• High or low blood pressure</li><li>• Vision disturbances</li><li>• Menstrual irregularities</li><li>• Unusually overactive</li><li>• Shaking and tremors</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<ul style="list-style-type: none"> <li>• Unusual hair loss or thinning</li> <li>• Swelling of hands, ankles or feet</li> <li>• Increased sensitivity of the skin to sun</li> <li>• 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 SETRONA.</li> <li>• Inflammation of the colon (causing diarrhea)</li> <li>• Laboratory abnormalities <ul style="list-style-type: none"> <li>• Lowered sodium content of the blood</li> <li>• Increased blood cholesterol, and sugar</li> <li>• Abnormal liver function test</li> <li>• Decreased blood uric acid levels</li> </ul> </li> </ul>	
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### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Symptoms of an allergic reaction may include rashes, hives, itching, difficulty breathing, shortness of breath or swelling of face, lips, tongue, hands/ feet, fainting, high temperature.</li> <li>• Severe skin reactions with blisters, sores or ulceration.</li> <li>• Marked behavioural changes including excessive excitement; abnormal body movements; combination of unresponsive body rigidity (inability to move or talk), high fever and profuse sweating.</li> <li>• Seizures or fits</li> <li>• Palpitations, fainting or chest pains</li> <li>• Symptoms of sudden fever with sweating, fast heart beat and muscle stiffness, which may lead to loss of consciousness</li> <li>• Marked changes in behaviour, emotions or mood including thoughts of suicide and self-harm, attempts at suicide.</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p> <p><b>These are very serious side effects. You may need urgent medical attention or hospitalisation. All these side effects are very rare.</b></p>

**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.

### 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](http://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 SETRONA contains

<b>Active ingredient (main ingredient)</b>	sertraline (as hydrochloride)
<b>Other ingredients (inactive ingredients)</b>	Microcrystalline cellulose, calcium hydrogen phosphate dihydrate, sodium starch glycollate, hypolose, magnesium stearate, and OPADRY complete film coating system OY-S-58910 WHITE (PI 11503).

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

### What SETRONA looks like

SETRONA 50 mg tablets are available in a pack of 30 tablets.

SETRONA 50 mg are white film coated caplet shaped tablets debossed with '50' on one side and a break-line on the other.

SETRONA 100 mg tablets are available in a pack of 30 tablets.

SETRONA 100 mg are white film coated caplet shaped tablets debossed with '100' on one side and a breakline on the other.

Australian Registration Numbers:

SETRONA 50 mg tablets – AUST R 116623

SETRONA 100 mg tablets – AUST R 116636

### Who distributes SETRONA

SETRONA is supplied in Australia by:

Sun Pharma ANZ Pty Ltd.

Macquarie Park NSW 2113

Australia

This leaflet was prepared in August 2022.